



Miltenyi Biotec

gentleMACS™ Octo Dissociator with Heaters

User manual



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gentleMACS™ Octo Dissociator with Heaters

User manual

Original instructions

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Read the chapter **Important safety information** and all other information in this user manual before using the instrument

 WARNING

Before using the gentleMACS Octo Dissociator with Heaters, read the chapter **Important safety information** and all other information contained in this user manual, including any safety and operating instructions. Pay special attention to all warnings displayed on the instrument. Failure to read and follow these guidelines could lead to improper or incorrect usage and result in damage to the instrument. Improper usage could also cause severe personal injury, death, unpredictable results, instrument malfunction, and premature wear to components shortening the lifetime of the instrument. Such actions may void your warranty. Keep the user manual and any other safety and operating instructions provided with the instrument in a safe place accessible to all users for future reference.

If you have a serious concern regarding the safe use of your instrument, contact your authorized Miltenyi Biotec service provider or call Miltenyi Biotec Technical Support.

Supported instruments

This user manual applies to the gentleMACS Octo Dissociator with Heaters (# 130-134-029) running with the gentleMACS Software version 1.2.

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General safety instructions



THIS CHAPTER DESCRIBES POTENTIALLY HAZARDOUS SITUATIONS ASSOCIATED WITH THIS INSTRUMENT AND PROVIDES IMPORTANT SAFETY INFORMATION TO MINIMIZE THE RISKS AND PROTECT YOURSELF AND OTHERS.

This chapter provides important information for your personal safety and the correct use of the instrument. Read and observe all instructions carefully before proceeding with the installation and use of the instrument. Observe general safety practices in addition to this user manual.

- Use this instrument only as indicated in this user manual to avoid personal injury and property damage.
- Keep this user manual in a place that is always accessible to all users.
- Observe local working area safety instructions and laboratory policies, as well as standards for health, safety, and prevention of accidents.
- In case of severe accidents, damages to the instrument, or if smoke or flames appear, cut the power supply immediately.
- To entirely disconnect the instrument from the power supply, unplug the power cable.
- Ensure that the power switch and the plug of the power cable of the instrument are easily accessible.

Hazard levels

Signal words are used to warn against hazardous situations and property damages. The following signal words are used in this user manual.

⚠ WARNING or **WARNING!** indicates a hazardous situation that, if not avoided, could result in death or serious injury.

⚠ CAUTION or **CAUTION!** indicates a hazardous situation that, if not avoided, could result in minor or moderate injury. It is also used to warn against unsafe practices.

NOTICE or **NOTICE** indicates information considered important but not hazard related (e.g. messages relating to property damage).

Symbols



SAFETY WARNING: THE DOCUMENTATION MUST BE CONSULTED IN ALL CASES WHERE THIS SAFETY SYMBOL IS USED ON THE INSTRUMENT



HOT SURFACE



ROTATING PARTS



ON (POWER ON)



OFF (POWER OFF)



READ THE USER MANUAL BEFORE USING THE INSTRUMENT



FUSE



WEEE (WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT)



ORDER NUMBER



TYPE NUMBER



SERIAL NUMBER



MANUFACTURER



DATE OF MANUFACTURE



EUROPEAN CONFORMITY MARKING



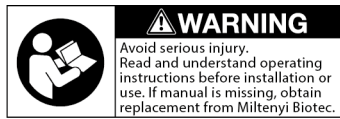
UNITED KINGDOM CONFORMITY ASSESSED MARKING



NRTL CERTIFICATION MARK: PRODUCT MEETS CONSENSUS-BASED STANDARDS OF SAFETY, REQUIRED BY THE OCCUPATIONAL SAFETY/HEALTH ADMINISTRATION (OSHA), DETERMINED BY THE NATIONALLY RECOGNIZED TESTING LABORATORIES (NRTL) TÜV SÜD

Safety labels

Notice the hazard points and safety symbols of the instrument. Keep safety labels and safety markings clean and legible. Inspect the safety labels and safety markings regularly and replace them if they are not legible or identifiable from a safe viewing distance. Contact Miltenyi Biotec for replacement labels. The following safety label is attached to the back of the instrument and plays an important part in maintaining safety.



WARNING! Avoid serious injury. Read and understand operating instructions before installing or use. If manual is missing, obtain replacement from Miltenyi Biotec.

The gentleMACS Sleeves are marked with a contrasting safety print. The contrasting safety print allows the visual perception of the rotation of the gentleMACS Sleeves. The gentleMACS Octo Trough is marked with the following safety symbol.



Figure 1: Safety symbol on the gentleMACS Octo Trough and contrasting safety print on the gentleMACS Sleeves

- 1 Contrasting safety print on the gentleMACS Sleeves
- 2 Safety symbol on the gentleMACS Octo Trough

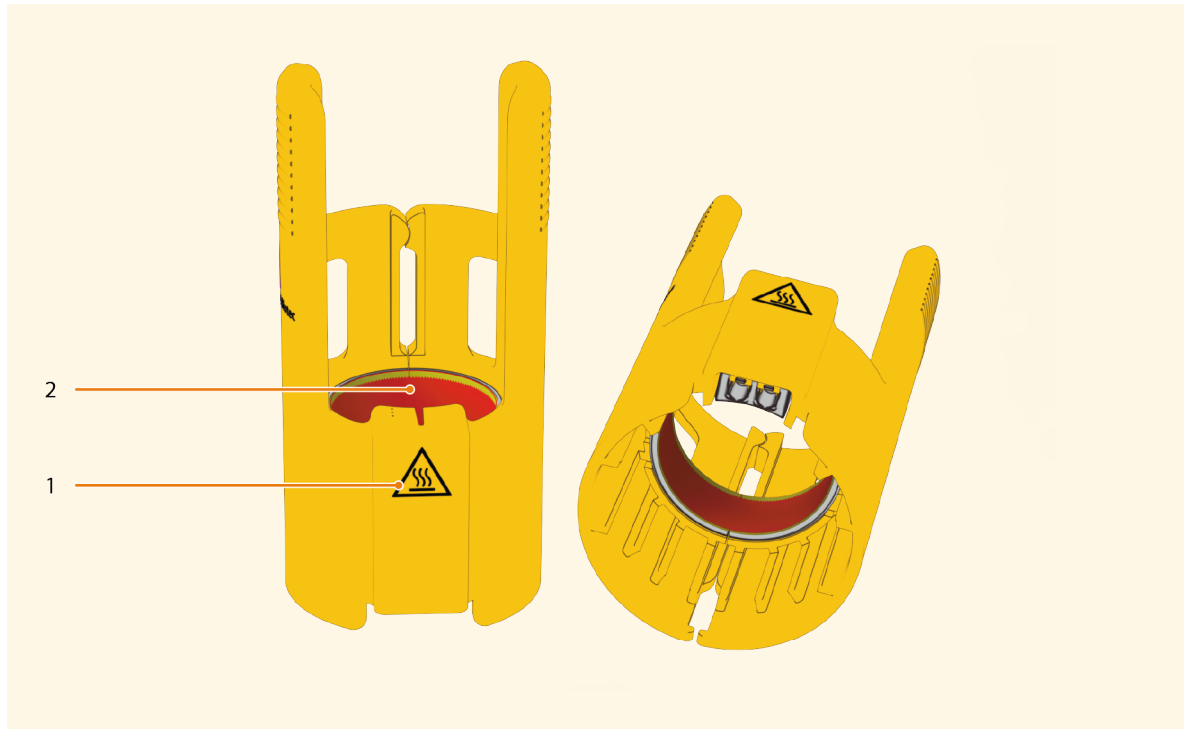


Figure 2: Safety symbol on the gentleMACS Heaters

- 1 Safety symbol on the gentleMACS Heaters
- 2 Heating foil

Electrical hazards

⚠ WARNING

Electric shock, short circuit, overheating, fire, and explosion could result in death or serious injury.

Protective housing

The housing of the instrument reduces the risk of an electric shock and short circuits.

- Do not remove or penetrate any cover of the housing.
- Exceptions are maintenance procedures that are explicitly described in this manual.
- Do not use the instrument if it is opened or disassembled.
- Do not use the instrument if an object entered the inside of the instrument.
- Check the instrument before each use for visible damages.
- Do not use the instrument if it has been dropped or is damaged.

Cables and power supplies

Using the instrument with other than the supplied cables is potentially hazardous.

- Only use the included power cable.
- Do not use the instrument if the power cable is damaged.
- The instrument has a three-wire electrical grounding plug with a third pin for grounding.
- Only insert the plug into a grounded electrical outlet. Do not try to insert the plug into a non-grounded electrical outlet.
- Operate the instrument only from a power source that meets the electrical specifications mentioned on the type label. If you have questions about the type of power source to use, contact the Miltenyi Biotec Technical Support or your local electricity supplier.

Liquids inside the instrument

Liquids inside the instrument can cause short circuits.

- Protect the instrument against spilled liquids.
- Do not use the instrument if liquids have entered the inside of the instrument.
- If liquids have entered the instrument, unplug the instrument and contact Miltenyi Biotec Technical Support.
- Clean up spilled liquids immediately.
- Unplug the instrument before cleaning it.
- Use only small amounts of cleaning agents on a soft cloth to wipe the instrument. Do not spray or pour liquid cleaning agents onto or into the instrument.

Mechanical hazards

CAUTION

Risk of crushing.

The instrument will fall down if it is not placed on a flat and even surface, which could result in injuries.

- Place the instrument only onto stable, even, and vibration free tables or laboratory benches.
- Handle the instrument with care during carrying or relocation.

CAUTION

Risk of crushing or cutting.

gentleMACS Tube caps have sharp edges on the inside. This may lead to incision wounds if they were touched while rotating.

- Only use tightly closed tubes and ensure that they are properly installed.
- Do not install or remove tubes while the rotors of the instrument are in motion.

CAUTION

Risk of trapping fingers and hair pulled in.

Hair can be pulled in by the rotors when the instrument is running.

- Do not operate the instrument without gentleMACS Octo Trough, gentleMACS Sleeves, and gentleMACS Octo Safety Shield.
- Tie back long hair.
- Do not touch the rotors while the instrument is running.

Biological hazards

WARNING

Contamination or infection could result in death or serious injury depending on the material used.

Biological material

All biological material must be considered potentially infectious.

- Wear personal protective equipment (such as gloves, safety glasses, etc.) as indicated in the safety data sheet for the particular substance.
- Operate the instrument in a safety hood if hazardous or potentially infectious materials are processed.
- Decontaminate the instrument after processing hazardous or potentially infectious material.
- If hazardous or potentially infectious material has been spilled or leaked from the system, decontaminate the affected area.
- Use a disinfectant or cleaning agent that is appropriate for the specific pathogen or substance.

Waste

All liquid and solid waste must be considered hazardous.

- Observe local regulations regarding waste disposal.
- Autoclave or alternatively decontaminate waste with an appropriate disinfectant.

Chemical hazards

WARNING

Substances and reagents can be hazardous.

- All safety measures in section **Biological hazards** also apply to any hazardous substances and reagents that may be present in the sample.
- Operate the instrument in a fume hood if hazardous substances and reagents are processed.

Thermal hazards

CAUTION

Hot surfaces can cause burns.

When the heating function is used, the heating foil of the gentleMACS Heaters becomes hot.

- Do not touch the heating foil.

Noise

CAUTION

High noise levels could result in hearing impairment.

If running with maximum load, the instrument may produce loud noise. It is recommended that the responsible body measures or calculates the sound pressure level at the operator's position and at whatever point 1 m from the enclosure of the equipment has the highest sound pressure level.

- Noise level should be below 70 dB.
- Observe local regulations regarding hearing protection.
- If running the instrument with maximum load, then protective safety equipment such as noise reducing baffles or hoods, or ear protection has to be used.

Servicing and transportation

Servicing

Improper servicing or repair of the instrument or use of unauthorized parts can cause malfunction of or damage to the instrument. This can cause hazards to users.

- Unless otherwise specifically stated in this user manual or other documentation by Miltenyi Biotec, do not service the instrument yourself.
- Servicing and repair must be performed by Miltenyi Biotec certified and qualified service personnel.
- If the instrument needs servicing, decontaminate the instrument to remove any hazardous material.
- If you have questions regarding proper decontamination or shipment, contact Miltenyi Biotec Technical Support for assistance.
- Only use accessories and upgrades recommended by Miltenyi Biotec.
- Inquire with your local Miltenyi Biotec representative about Miltenyi Biotec's extensive instrument service and service contracts, or refer to **www.miltenyibiotec.com/support**.

Transportation

The instrument must be transported with care in packaging specified by Miltenyi Biotec. Internal damage could occur if the instrument is subjected to excessive vibration or if it is dropped. If the instrument needs to be shipped back to the manufacturer for service, contact Miltenyi Biotec for instructions and packaging materials.

Disposal



WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE) CUSTOMER INFORMATION

Dispose of your end-of-life Miltenyi Biotec products in accordance with the applicable WEEE and hazardous waste disposal legislation, which may differ by country or region. Electrical equipment may contain hazardous substances that may have a serious detrimental effect on the environment and/or human health. All equipment must be specifically collected and treated by designated waste facilities and by qualified WEEE compliance schemes. By ensuring that you dispose of your unwanted electrical and electronic equipment according to the applicable WEEE and hazardous waste disposal legislation, you are helping to preserve our natural resources and protect human health. Miltenyi Biotec is committed to protecting the environment. Miltenyi Biotec offers product end-of-life return programs in many countries and partners with licensed WEEE compliance schemes throughout the world. Miltenyi Biotec takes back your end-of-life Miltenyi Biotec equipment for recycling free of charge. The terms and availability of this offer vary by geography because of differences in regulatory requirements. Note that, depending on the type and use of your equipment, additional requirements may apply. Before shipping the instrument back to the manufacturer for disposal, decontaminate the instrument to remove any hazardous material. For more information or if you wish to dispose of your end-of-life Miltenyi Biotec equipment, contact your local Miltenyi Biotec representative or Miltenyi Biotec Technical Support.

EN				
DE				
ES				
FR				
IT				



Allgemeine Sicherheitshinweise

DIESES KAPITEL BESCHREIBT POTENZIELL GEFÄHRLICHE SITUATIONEN IM ZUSAMMENHANG MIT DIESEM GERÄT UND ENTHÄLT WICHTIGE SICHERHEITSHINWEISE, UM RISIKEN ZU MINIMIEREN UND SICH SELBST UND ANDERE ZU SCHÜTZEN.

Dieses Kapitel enthält wichtige Informationen für Ihre persönliche Sicherheit und die richtige Verwendung des Instruments. Lesen und beachten Sie alle Anweisungen sorgfältig, bevor Sie mit der Installation und Verwendung des Instruments fortfahren. Beachten Sie zusätzlich zu diesem Benutzerhandbuch die allgemeinen Sicherheitsvorschriften.

- Verwenden Sie das Gerät nur wie in diesem Benutzerhandbuch angegeben, um Personen- und Sachschäden zu vermeiden.
- Bewahren Sie dieses Benutzerhandbuch an einem Ort auf, der jederzeit für alle Benutzer zugänglich ist.
- Beachten Sie die lokal geltenden Arbeitsschutzvorschriften und Laborrichtlinien sowie die gesetzlich geregelten Maßnahmen zu Sicherheit, Gesundheitsschutz und Unfallverhütung.
- Bei schweren Unfällen, Beschädigungen des Gerätes, Rauch oder Flammen unterbrechen Sie sofort die Stromversorgung.
- Ziehen Sie den Netzstecker, um das Gerät vollständig von der Stromversorgung zu trennen.
- Stellen Sie sicher, dass der Hauptschalter und der Netzstecker des Gerätes leicht zugänglich sind.

Gefahrenstufen

Es werden Signalwörter verwendet, um vor Gefahrensituationen und Sachschäden zu warnen. In diesem Benutzerhandbuch werden die folgenden Signalwörter verwendet.

⚠️ WARNUNG oder **WARNUNG!** weist auf eine Gefahrensituation hin, die, falls sie nicht vermieden wird, zum Tod oder zu schweren Verletzungen führen kann.

⚠️ VORSICHT oder **VORSICHT!** weist auf eine Gefahrensituation hin, die, falls sie nicht vermieden wird, zu leichten oder mittelschweren Verletzungen führen kann. Dies wird auch dazu verwendet, um auf unsichere Vorgehensweisen hinzuweisen.

HINWEIS oder **HINWEIS** weist auf wichtige, jedoch nicht gefahrenbezogene Informationen hin (z. B. Hinweise in Verbindung mit Sachschäden).

Symbole



SICHERHEITSWARNUNG: BEACHTEN SIE DIE DOKUMENTATION IMMER, WENN DIESES WARNSYMBOL AM GERÄT VERWENDET WIRD



HEIßE OBERFLÄCHE



SICH DREHENDE TEILE



EIN (EINGESCHALTET)



AUS (AUSGESCHALTET)



LESEN SIE DAS BENUTZERHANDBUCH VOR VERWENDUNG DES GERÄTES



SICHERUNG



ELEKTRO- UND ELEKTRONIK-ALTGERÄTE (WEEE)



BESTELLNUMMER



MODELLNUMMER



SERIENNUMMER



HERSTELLER



HERSTELLUNGSDATUM



EUROPÄISCHE KONFORMITÄTSKENNZEICHNUNG



BRITISCHE PRODUKTKENNZEICHNUNG



NRTL-PRÜFZEICHEN: DAS PRODUKT ENTSPRICHT DEN IM KONSENSVERFAHREN ERARBEITETEN SICHERHEITSANFORDERUNGEN, WELCHE VON DER OCCUPATIONAL SAFETY/HEALTH ADMINISTRATION (OSHA) GEFORDERT UND VON DER STAATLICH ANERKANNTEN PRÜFSTELLE (NATIONALLY RECOGNIZED TESTING LABORATORIES (NRTL)) TÜV SÜD GEPRÜFT WURDEN

Sicherheitskennzeichnungen

Beachten Sie die Gefahrenhinweise und Sicherheitssymbole des Gerätes. Halten Sie die Warnaufkleber und Sicherheitskennzeichnungen sauber und lesbar. Überprüfen Sie die Warnaufkleber und Sicherheitskennzeichnungen regelmäßig und ersetzen Sie diese, wenn sie nicht mehr lesbar oder aus sicherer Entfernung nicht zu erkennen sind. Kontaktieren Sie Miltenyi Biotec, um Ersatzaufkleber zu erhalten. Der folgende Sicherheitsaufkleber ist auf der Rückseite des Geräts angebracht und spielt eine wichtige Rolle bei der Aufrechterhaltung der Sicherheit.



WARNUNG! Vermeiden Sie schwere Verletzungen. Vor der Installation oder Inbetriebnahme ist die Bedienungsanleitung zu lesen. Wenn die Anleitung fehlt, fordern Sie Ersatz bei Miltenyi Biotec an.

Die gentleMACS Sleeves sind mit einem kontrastierenden Warnaufdruck gekennzeichnet. Der kontrastierende Warnaufdruck macht die Drehung der gentleMACS Sleeves sichtbar. Der gentleMACS Octo Trough ist mit dem folgenden Sicherheitssymbol gekennzeichnet.



Abbildung 1: Sicherheitssymbol auf dem gentleMACS Octo Trough und farblich abgesetzter Sicherheitsaufdruck auf den gentleMACS Sleeves

- 1 Farblich abgesetzter Sicherheitsaufdruck auf den gentleMACS Sleeves
- 2 Sicherheitssymbol auf dem gentleMACS Octo Trough

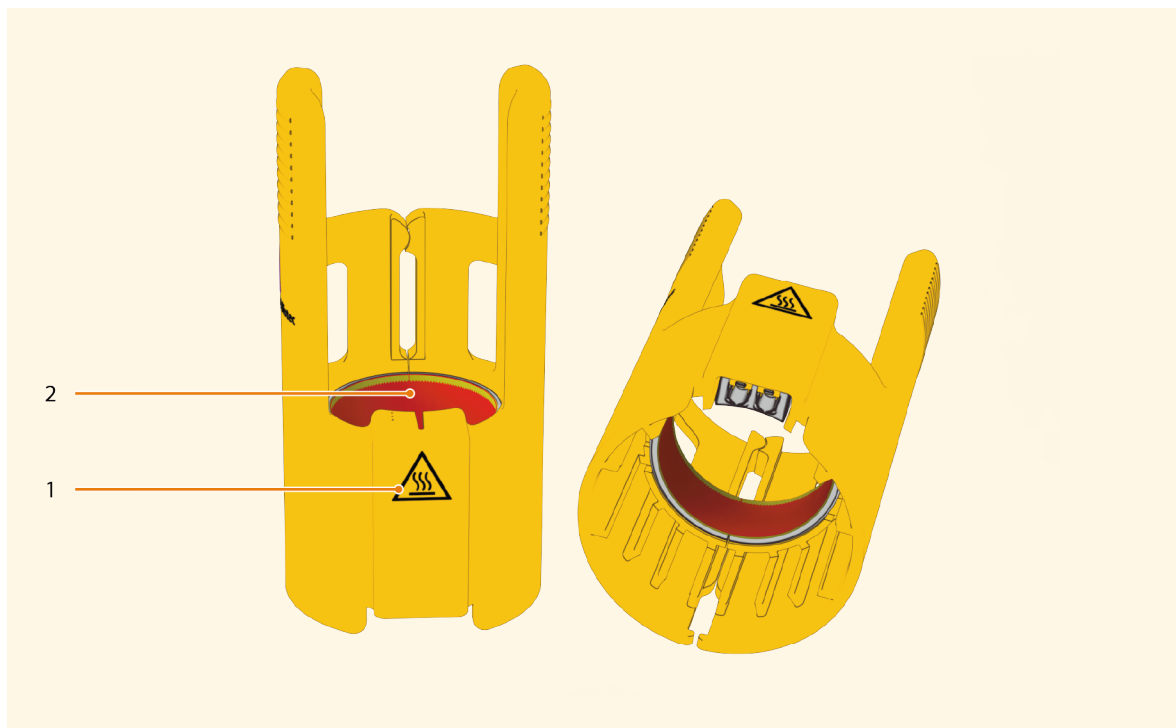


Figure 2: Sicherheitssymbol auf den gentleMACS Heaters

- 1 Sicherheitssymbol auf den gentleMACS Heaters
- 2 Heizfolie

Elektrische Gefahren

⚠️ WARNUNG

Stromschlag, Kurzschluss, Überhitzung, Feuer und Explosion können zu schweren Verletzungen oder zum Tod führen.

Schützendes Gehäuse

Das Gehäuse des Gerätes reduziert das Risiko eines Stromschlags und von Kurzschlüssen.

- Entfernen oder öffnen Sie niemals Teile des Gehäuses.
- Ausnahmen hiervon sind ausdrücklich in diesem Handbuch beschriebene Wartungsvorgänge.
- Verwenden Sie das Gerät nicht, wenn es geöffnet oder demontiert ist.
- Verwenden Sie das Gerät nicht, wenn ein Objekt hineingefallen ist.
- Das Instrument vor jedem Gebrauch auf sichtbare Schäden überprüfen.
- Verwenden Sie das Gerät nicht, wenn es heruntergefallen oder beschädigt ist.

Kabel und Stromversorgung

Die Verwendung des Gerätes mit anderen als den mitgelieferten Kabeln ist potenziell gefährlich.

- Verwenden Sie nur das mitgelieferte Netzkabel.
- Verwenden Sie das Gerät nicht, wenn das Netzkabel beschädigt ist.
- Das Gerät verfügt über einen dreiadrigen elektrischen Erdungsstecker mit einem dritten Stift zur Erdung.
- Stecken Sie den Stecker nur in eine geerdete Steckdose. Versuchen Sie nicht, den Stecker an eine nicht geerdete Steckdose anzuschließen.

- Betreiben Sie das Gerät nur an einer Stromquelle, die den auf dem Typenschild angegebenen elektrischen Spezifikationen entspricht. Bei Fragen zur zu verwendenden Stromquelle wenden Sie sich an einen autorisierten Miltenyi Biotec-Vertreter oder Ihren Stromversorger.

Flüssigkeiten im Inneren des Gerätes

Flüssigkeiten im Gerät können Kurzschlüsse verursachen.

- Schützen Sie das Gerät gegen verschüttete Flüssigkeiten.
- Verwenden Sie das Gerät nicht, wenn Flüssigkeiten in das Innere eingedrungen sind.
- Wenn Flüssigkeit in das Instrument eingedrungen ist, ziehen Sie den Netzstecker und wenden Sie sich an den Miltenyi Biotec Technical Support.
- Nehmen Sie verschüttete Flüssigkeiten sofort auf.
- Trennen Sie das Gerät vor der Reinigung von der Stromversorgung.
- Verwenden Sie nur geringe Mengen an Reinigungsmittel auf einem weichen Tuch, um das Gerät abzuwischen. Sprühen oder gießen Sie keine flüssigen Reinigungsmittel auf oder in das Gerät.

Mechanische Gefahren

VORSICHT

Gefahr von Quetschungen.

Das Gerät kann herunterfallen, wenn es nicht auf eine flache und ebene Fläche gestellt wird, was zu Verletzungen führen kann.

- Stellen Sie das Gerät nur auf stabile, ebene und vibrationsfreie Tische oder Labortische.
- Behandeln Sie das Gerät beim Tragen oder Umstellen mit Sorgfalt.

VORSICHT

Gefahr von Quetsch- oder Schnittverletzungen.

Die Deckel der gentleMACS Tubes sind innen scharfkantig. Dies kann zu Schnittwunden führen, wenn sie bei der Drehbewegung berührt werden.

- Verwenden Sie nur fest verschlossene Tubes und stellen Sie sicher, dass diese ordnungsgemäß eingesetzt sind.
- Wechseln Sie keine Tubes, während sich die Rotoren des Gerätes bewegen.

VORSICHT

Gefahr des Einklemmens von Fingern und des Einziehens von Haaren.

Haare können bei laufendem Gerät von den Rotoren eingezogen werden.

- Das Instrument nur mit gentleMACS Octo Trough, gentleMACS Sleeves und gentleMACS Octo Safety Shield betreiben.
- Langes Haar zurückbinden.
- Berühren Sie nicht die Rotoren während das Gerät läuft.

Biologische Gefahren

WARNUNG

Kontamination oder Infektion kann je nach verwendetem Material zu schweren Verletzungen oder zum Tod führen.

Biologisches Material

Alle biologischen Materialien müssen als potenziell infektiös eingestuft werden.

- Tragen Sie persönliche Schutzausrüstung (wie Handschuhe, Schutzbrille etc.), wie im Sicherheitsdatenblatt zum jeweiligen Material angegeben.
- Bei der Arbeit mit gefährlichen oder potenziell infektiösen Materialien betreiben Sie das Gerät in einer biologischen Sicherheitswerkbank.
- Dekontaminieren Sie das Gerät nach der Arbeit mit gefährlichen oder potenziell infektiösen Materialien.
- Wenn gefährliche oder potenziell infektiöse Materialien verschüttet wurden oder aus dem System ausgetreten sind, dekontaminieren Sie den betroffenen Bereich.
- Verwenden Sie kontaminiertes Zubehör oder kontaminierte Teile des Gerätes nicht weiter.

Abfall

Alle flüssigen und festen Abfälle müssen als gefährlich eingestuft werden.

- Beachten Sie die örtlichen Vorschriften zur Abfallentsorgung.
- Autoklavieren oder dekontaminieren Sie Abfall mit einem geeigneten Desinfektionsmittel.

Chemische Gefahren

WARNUNG

Stoffe und Reagenzien können gefährlich sein.

- Alle im Abschnitt **Biologische Gefahren** genannten Sicherheitsvorkehrungen gelten auch für gefährliche Stoffe und Reagenzien, die gegebenenfalls in der Probe enthalten sind.
- Betreiben Sie das Gerät unter einer Abzugshaube, wenn gefährliche Stoffe und Reagenzien verarbeitet werden.

Thermische Gefahren

VORSICHT

Heiße Oberflächen können zu Verbrennungen führen.

Bei Verwendung der Heizfunktion wird die Heizfolie der gentleMACS Heater heiß.

- Berühren Sie nicht die Heizfolie.

Lärm

VORSICHT

Hohe Geräuschpegel können zu Hörschäden führen.

Bei Betrieb mit maximaler Last kann das Instrument starke Geräusche erzeugen. Es wird empfohlen, den Schalldruckpegel an der Bedienposition und in einem Meter Abstand zu dem Punkt des Gerätes, an dem der höchste Schalldruckpegel herrscht, von der zuständigen Fachstelle messen oder berechnen zu lassen.

- Der Lärmpegel sollte unter 70 dB liegen.
- Beachte lokale Vorgaben zum Gehörschutz.

- Wird das Gerät unter Volllast betrieben, müssen Schutzeinrichtungen wie lärm-dämmende Leitbleche, Hauben oder Gehörschutz verwendet werden.

Wartung und Transport

Wartung

Unsachgemäße Wartung oder Reparatur des Gerätes oder die Verwendung von nicht zugelassenen Teilen kann zu Fehlfunktionen oder Schäden am Gerät führen. Dies kann zu Gefahren für den Benutzer führen.

- Soweit nicht ausdrücklich in diesem Handbuch oder anderen Unterlagen von Miltenyi Biotec erwähnt, darf das Gerät nicht vom Benutzer selbst gewartet oder repariert werden.
- Wartungs- und Reparaturarbeiten dürfen nur von Personen durchgeführt werden, die von Miltenyi Biotec zertifiziert und entsprechend qualifiziert sind.
- Vor der Wartung muss das Gerät dekontaminiert werden, um gefährliche Stoffe zu entfernen.
- Wenn Sie Fragen zur ordnungsgemäßen Dekontamination und dem Versand haben, kontaktieren Sie Miltenyi Biotec Technical Support.
- Verwenden Sie nur von Miltenyi Biotec empfohlene Zubehörteile und Upgrades.
- Wenn Sie mehr über das umfangreiche Serviceangebot und die Wartungsverträge in Verbindung mit den Geräten von Miltenyi Biotec erfahren möchten, wenden Sie sich an Ihren regionalen Miltenyi Biotec Vertreter oder besuchen Sie www.miltenyibiotec.com/support.

Transport

Das Gerät sollte immer vorsichtig und nur in der von Miltenyi Biotec vorgegebenen Verpackung transportiert werden. Muss das Gerät zur Wartung zurück an den Hersteller geschickt werden, so nehmen Sie bezüglich weiterer Anweisungen und der Verpackung Kontakt mit Miltenyi Biotec auf. Interne Beschädigungen können auftreten, wenn das Instrument übermäßigen Vibrationen ausgesetzt wird oder wenn es herunterfällt.

Entsorgung



KUNDENINFORMATION ZUR ENTSORGUNG VON ELEKTRO- UND ELEKTRONIK-ALTGERÄTEN (WEEE)

Entsorgen Sie Ihre Altgeräte von Miltenyi Biotec unter Einhaltung der jeweils geltenden Vorschriften für die Entsorgung von Elektro- und Elektronik-Altgeräten und die Entsorgung von Gefahrstoffen, die je nach Land oder Region unterschiedlich sein können. Elektrische Geräte können gefährliche Stoffe enthalten, welche die Umwelt erheblich belasten und/oder die Gesundheit gefährden. Sämtliche Altgeräte müssen gesondert gesammelt und von ausgewiesenen Abfallentsorgungseinrichtungen im Rahmen der hierfür vorgesehenen Entsorgungssysteme fachgerecht behandelt werden. Indem Sie sicherstellen, dass ihr Altgerät gemäß den geltenden Vorschriften zur Behandlung von Elektro- und Elektronik-Altgeräten sowie von Gefahrstoffen entsorgt wird, tragen Sie zum Erhalt unserer natürlichen Ressourcen und zum Schutz der menschlichen Gesundheit bei. Miltenyi Biotec hat sich dem Schutz der Umwelt verpflichtet. Miltenyi Biotec bietet in zahlreichen Ländern Rücknahmeprogramme für Altgeräte an und arbeitet weltweit mit lizenzierten Partnern zusammen, die an bestehende Recycling- und Entsorgungssysteme angeschlossen sind. Miltenyi Biotec ermöglicht Ihnen ein kostenloses Recycling Ihres Altgerätes. Die Bedingungen und die Verfügbarkeit dieses Angebots unterscheiden sich geographisch aufgrund unterschiedlicher regulatorischer Anforderungen. Beachten Sie, dass je nach Art und Nutzung Ihres Gerätes zusätzliche Anforderungen gelten können. Bevor Sie das Altgerät an den Hersteller zur Entsorgung zurücksenden, dekontaminieren Sie es, um sämtliche gefährlichen Stoffe zu entfernen. Für weitere Informationen oder wenn Sie Altgeräte von Miltenyi Biotec entsorgen möchten, wenden Sie sich an Ihren lokalen Vertreter von Miltenyi Biotec oder an den Miltenyi Biotec Technical Support.

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Instrucciones generales de seguridad

EN ESTE CAPÍTULO SE DESCRIBEN SITUACIONES POTENCIALMENTE PELIGROSAS ASOCIADAS CON ESTE INSTRUMENTO Y SE PROPORCIONA INFORMACIÓN IMPORTANTE SOBRE SEGURIDAD PARA MINIMIZAR LOS RIESGOS Y PROTEGERSE A SÍ MISMO Y A LOS DEMÁS.

Este capítulo ofrece información importante para su seguridad personal y el correcto uso del instrumento. Lea y siga todas las instrucciones atentamente antes de la instalación y el uso del instrumento. Siga las prácticas de seguridad generales además de este manual de uso.

- Use este instrumento solo como se indica en este manual de uso para evitar lesiones personales y daños materiales.
- Guarde este manual de uso en un lugar que siempre esté accesible para todos los usuarios.
- Observe las instrucciones de seguridad de la zona de trabajo local y las políticas de laboratorio, así como las normas de salud, seguridad y prevención de accidentes.
- En caso de accidentes graves, daños en el instrumento o si aparece humo o llamas, corte de inmediato el suministro de la corriente eléctrica.
- Para desconectar completamente el instrumento del suministro de la corriente eléctrica, desenchufe el cable de alimentación.
- Asegúrese de que se pueda acceder fácilmente al interruptor de corriente y al enchufe del cable de alimentación del instrumento.

Niveles de riesgo

Las palabras de advertencia se utilizan para advertir contra situaciones peligrosas y daños materiales. En este manual de uso se utilizan las siguientes palabras de advertencia.

⚠ ADVERTENCIA o ¡ADVERTENCIA! indica una situación peligrosa que, de no evitarse, podría conllevar la muerte o lesiones graves.

⚠ ATENCIÓN o ¡ATENCIÓN! indica una situación peligrosa que, de no evitarse, podría conllevar lesiones leves o moderadas. También sirve para advertir sobre prácticas poco seguras.

AVISO o AVISO indica información que se considera importante, pero no relacionada con un peligro (p. ej., mensajes relacionados con daños materiales).

Símbolos



ADVERTENCIA DE SEGURIDAD: SE DEBE CONSULTAR LA DOCUMENTACIÓN EN TODOS LOS CASOS EN QUE SE UTILICE ESTE SÍMBOLO DE SEGURIDAD EN EL INSTRUMENTO



SUPERFICIE CALIENTE



PIEZAS GIRATORIAS



ON (ENCENDIDO)



OFF (APAGADO)



LEA EL MANUAL DEL USUARIO ANTES DE UTILIZAR EL INSTRUMENTO



FUSIBLE



INFORMACIÓN AL CLIENTE SOBRE LA DIRECTIVA DE RESIDUOS DE APARATOS ELÉCTRICOS Y ELECTRÓNICOS (RAEE)



NÚMERO DE PEDIDO



NÚMERO DEL MODELO



NÚMERO DE SERIE



FABRICANTE



FECHA DE FABRICACIÓN



MARCADO DE CONFORMIDAD EUROPEA



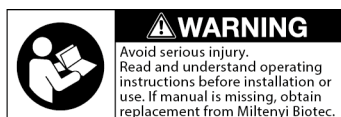
CONFORMIDAD EVALUADA DEL REINO UNIDO



MARCA DE CERTIFICACIÓN NRTL: EL PRODUCTO CUMPLE LOS ESTÁNDARES DE SEGURIDAD CONSENSUADOS, REQUERIDOS POR LA ADMINISTRACIÓN DE SEGURIDAD Y SALUD OCUPACIONAL (OSHA), DETERMINADOS POR LOS LABORATORIOS DE ENSAYO RECONOCIDOS NACIONALMENTE (NATIONALLY RECOGNIZED TESTING LABORATORIES, NRTL) TÜV SÜD

Etiqueta de seguridad

Observe los puntos de peligro y los símbolos de seguridad del instrumento. Mantenga las etiquetas y marcas de seguridad en un estado limpio y legible. Inspeccione las etiquetas y marcas de seguridad con regularidad, y reemplácelas si no son legibles o identificables desde una distancia de visualización segura. Póngase en contacto con Miltenyi Biotec si necesita etiquetas de recambio. La siguiente etiqueta de seguridad se encuentra pegada en la parte posterior del instrumento y juega un papel importante en el mantenimiento de la seguridad.



ADVERTENCIA! Evita las lesiones graves. Lea y comprenda las instrucciones de funcionamiento antes de la instalación o el uso. Si falta el manual, solicite su sustitución a Miltenyi Biotec.

Los gentleMACS Sleeves están marcados con una impresión de seguridad de contraste. La impresión de seguridad de contraste permite la percepción visual de la rotación de los gentleMACS Sleeves. El gentleMACS Octo Trough va marcado con el siguiente símbolo de seguridad.



Figura 1: Símbolo de seguridad en el gentleMACS Octo Trough y estampado de seguridad en contraste en los gentleMACS Sleeves

- 1 Estampado de seguridad en contraste en los gentleMACS Sleeves
- 2 Símbolo de seguridad en el gentleMACS Octo Trough

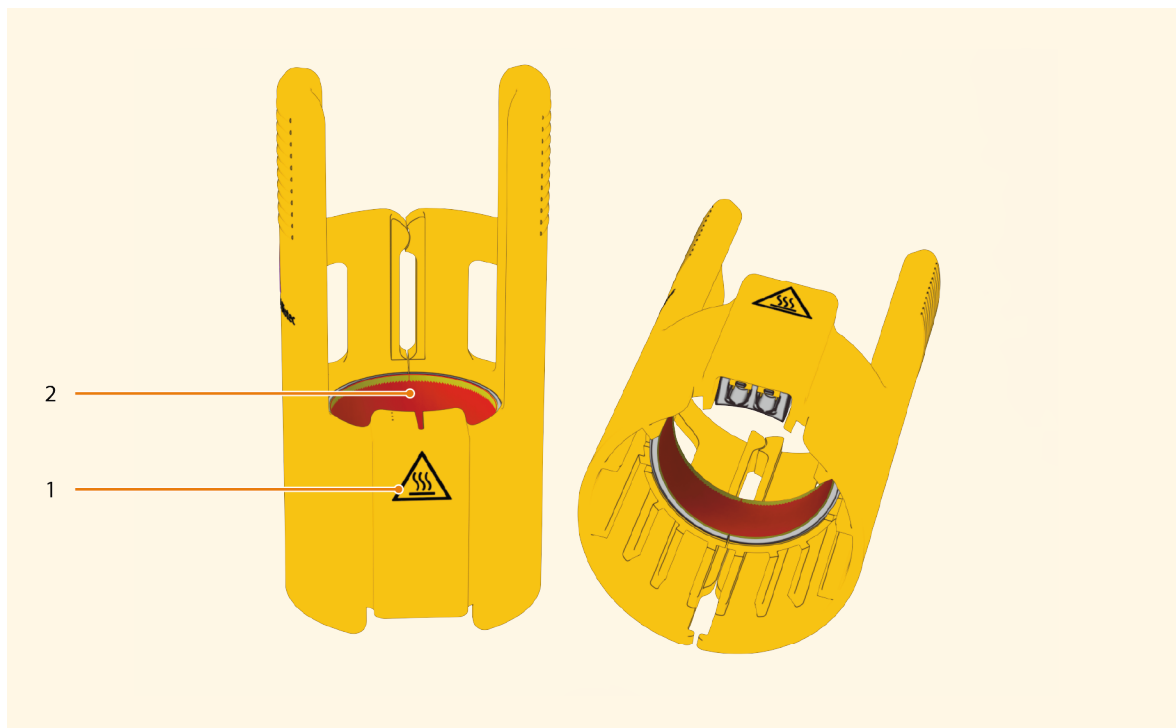


Figure 2: Símbolo de seguridad en los gentleMACS Heaters

- 1 Símbolo de seguridad en los gentleMACS Heaters
- 2 Lámina calefactada

Peligros eléctricos

⚠ ADVERTENCIA

Una descarga eléctrica, un cortocircuito, un sobrecalentamiento, un incendio o una explosión podría causar la muerte o lesiones graves.

Carcasa protectora

La carcasa del instrumento reduce el riesgo de un shock eléctrico y cortocircuitos.

- No retire ni perforo ninguna cubierta de la carcasa.
- Las excepciones son los procesos de mantenimiento que se describen explícitamente en este manual.
- No utilice el instrumento si se ha abierto o desmontado.
- No utilice el instrumento si un objeto ha entrado en el interior del mismo.
- Antes de cada uso, revise el instrumento para ver si presenta daños visibles.
- No utilice el instrumento si se ha caído o dañado.

Cables y suministros de corriente eléctrica

Usar el instrumento con otros cables que no sean los suministrados es potencialmente peligroso.

- Utilice únicamente el cable de alimentación incluido.
- No utilice el instrumento si el cable de alimentación está dañado.
- El instrumento tiene un enchufe eléctrico de tres hilos con una tercera clavija para la conexión a tierra.
- Inserte el enchufe solo en una toma de corriente con conexión a tierra. No intente insertar el enchufe en una toma de corriente sin conexión a tierra.

- Utilice el instrumento solo con una fuente de alimentación que cumpla las especificaciones eléctricas mencionadas en la placa de identificación. Si tiene alguna pregunta sobre la fuente de alimentación que debe utilizarse, póngase en contacto con el Miltenyi Biotec Technical Support o con la compañía eléctrica local.

Líquidos en el interior del instrumento

Los líquidos que hay dentro del instrumento pueden provocar cortocircuitos.

- Proteja el instrumento contra líquidos derramados.
- No utilice el instrumento si ha entrado algún líquido en el interior del instrumento.
- Si han entrado líquidos en el instrumento, desenchúfelo y póngase en contacto con Miltenyi Biotec Technical Support.
- Limpie los líquidos derramados inmediatamente.
- Desenchufe el instrumento antes de limpiarlo.
- Use solo pequeñas cantidades de productos de limpieza en un paño suave para limpiar el instrumento. No rocíe ni vierta productos de limpieza líquidos sobre o dentro del instrumento.

Peligros mecánicos

ATENCIÓN

Riesgo de aplastamiento.

El instrumento se caerá si no se coloca sobre una superficie plana y uniforme, lo que podría causar lesiones.

- Coloque el instrumento sobre una mesa o bancada de laboratorio estable, uniforme y sin vibraciones.
- Manipule el instrumento con cuidado al transportarlo o trasladarlo.

ATENCIÓN

Riesgo de aplastamiento o corte.

Los tapones de los Tubos gentleMACS tienen bordes afilados en el interior. Pueden causar heridas por incisión si se tocan mientras giran.

- Utilice únicamente tubos bien cerrados y asegúrese de que estén correctamente instalados.
- No instale ni retire tubos mientras los rotores del instrumento están en movimiento.

ATENCIÓN

Riesgo de atrapamiento de los dedos y el cabello.

Los rotores pueden arrastrar el cabello mientras el instrumento está en funcionamiento.

- No utilice el instrumento sin el gentleMACS Octo Trough, los gentleMACS Sleeves ni el gentleMACS Octo Safety Shield.
- Recoge el pelo largo.
- No toque los rotores mientras el instrumento está en funcionamiento.

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Peligros biológicos

ADVERTENCIA

La contaminación o infección podría causar la muerte o lesiones graves en función del material utilizado.

Material biológico

Todo material biológico debe considerarse potencialmente infeccioso.

- Use equipo de protección personal (como guantes, gafas de seguridad, etc.) como se indica en la hoja de datos de seguridad de la sustancia en particular.
- Maneje el instrumento en una cubierta de seguridad si se procesan materiales peligrosos o potencialmente infecciosos.
- Descontamine el instrumento después de procesar material peligroso o potencialmente infeccioso.
- Si se ha derramado o fugado del sistema un material peligroso o potencialmente infeccioso, descontamine el área afectada.
- Use un desinfectante o producto de limpieza que sea apropiado para el patógeno o sustancia en cuestión.

Desechos

Todos los desechos líquidos y sólidos deben ser considerados peligrosos.

- Observe las regulaciones locales sobre la eliminación de desechos.
- Ponga en autoclave o, como alternativa, descontamine los desechos con un desinfectante apropiado.

Peligros químicos

ADVERTENCIA

Las sustancias y los reactivos pueden ser peligrosos.

- Todas las medidas de seguridad del apartado **Peligros biológicos** se aplican también a todas las sustancias y reactivos peligrosos que puedan estar presente en la muestra.
- Utilice el instrumento en una campana para vapores si se procesan sustancias y reactivos peligrosos.

Peligros térmicos

ATENCIÓN

Las superficies calientes pueden causar quemaduras.

Cuando se utiliza la función de calentamiento, la lámina de calentamiento de los gentleMACS Heaters se calienta.

- No toque la lámina de calentamiento.

Ruido

ATENCIÓN

Un alto nivel de ruido puede conllevar una pérdida auditiva.

Si se utiliza con la carga máxima, el instrumento puede producir un ruido fuerte. Se recomienda que el cuerpo responsable mida o calcule el nivel de presión acústica en el puesto del operario y en cualquier punto a 1 metro del recinto del equipo que tenga el mayor nivel de presión acústica.

- El nivel de ruido debe ser inferior a 70 dB.
- Observe las normas locales sobre protección auditiva.

- Si se utiliza el instrumento con la carga máxima, se debe usar equipo de seguridad de protección como, por ejemplo, deflectores que reduzcan el ruido, cubiertas o protección auditiva.

Reparación y transporte

Reparación

La reparación inadecuada del instrumento o el uso de piezas no autorizadas pueden provocar un mal funcionamiento o daños en el instrumento. Esto puede constituir un peligro para los usuarios.

- A menos que se indique específicamente lo contrario en este manual del usuario o en otros documentos de Miltenyi Biotec, no realice usted mismo los trabajos de mantenimiento y reparación del instrumento.
- La reparación debe ser realizada por personal de servicio cualificado y certificado por Miltenyi Biotec.
- Si el instrumento necesita reparación, descontámelo para eliminar cualquier material peligroso.
- Si tiene alguna pregunta relativa a la descontaminación o el envío adecuados, póngase en contacto con el Miltenyi Biotec Technical Support para que le ayuden.
- Utilice solo accesorios y actualizaciones recomendados por Miltenyi Biotec.
- Consulte a su representante local de Miltenyi Biotec sobre el amplio servicio de reparaciones de instrumentos y los contratos de reparaciones de Miltenyi Biotec, o visite **www.miltenyibiotec.com/support**.

Transporte

El instrumento deberá transportarse con cuidado en el embalaje especificado por Miltenyi Biotec. Se podrían producir daños internos si el instrumento se somete a un exceso de vibraciones o se cae. Si es necesario enviar el instrumento al fabricante para su reparación, comuníquese con Miltenyi Biotec para obtener instrucciones y materiales de embalaje.

Eliminación



INFORMACIÓN AL CLIENTE SOBRE LA DIRECTIVA DE RESIDUOS DE APARATOS ELÉCTRICOS Y ELECTRÓNICOS (RAEE)

Elimine los productos de Miltenyi Biotec al final de su vida útil de acuerdo con la legislación aplicable en materia de eliminación de residuos peligrosos y RAEE, que puede variar según el país o la región. El equipo eléctrico puede contener sustancias peligrosas que pueden tener un efecto perjudicial grave en el medio ambiente y/o la salud humana. Todo el equipo debe ser recogido y tratado específicamente en instalaciones de desechos designadas y en sistemas conformes a la legislación sobre RAEE. Al asegurarse de desechar sus aparatos eléctricos y electrónicos no deseados de acuerdo con la legislación aplicable sobre eliminación de desechos peligrosos y RAEE, está ayudando a preservar nuestros recursos naturales y proteger la salud humana. Miltenyi Biotec se compromete a proteger el medio ambiente. Miltenyi Biotec ofrece programas de devolución de productos al final de su vida útil en muchos países y socios con licencia que disponen de sistemas conformes a la legislación sobre RAEE en todo el mundo. Miltenyi Biotec recoge su equipo Miltenyi Biotec al final de su vida útil para reciclarlo de forma gratuita. Los términos y la disponibilidad de esta oferta pueden variar según la región geográfica, debido a las diferencias en los requisitos reglamentarios. Tenga en cuenta que, dependiendo del tipo y uso del equipo, pueden aplicarse requisitos adicionales. Antes de devolver el instrumento al fabricante para que lo deseche, descontamine el instrumento para eliminar cualquier material peligroso. Para obtener más información, o si desea desechar su equipo Miltenyi Biotec al final de su vida útil, póngase en contacto con su representante local de Miltenyi Biotec o con el Miltenyi Biotec Technical Support.

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Instructions générales de sécurité

CE CHAPITRE DÉCRIT LES SITUATIONS POTENTIELLEMENT DANGEREUSES ASSOCIÉES À CET INSTRUMENT ET FOURNIT DES INFORMATIONS DE SÉCURITÉ IMPORTANTES DESTINÉES À RÉDUIRE LES RISQUES ET À VOUS PROTÉGER AINSI QU'À PROTÉGER LES AUTRES.

Le présent chapitre donne des informations importantes pour votre sécurité personnelle et pour l'utilisation correcte de l'instrument. Veuillez lire attentivement toutes les instructions et les retenir avant de procéder à l'installation de l'instrument et d'utiliser celui-ci. Appliquez les mesures de sécurité générales en plus de celles exposées dans le manuel d'utilisation.

- Utilisez toujours cet instrument en suivant les indications fournies dans ce manuel d'utilisation, afin d'éviter toute blessure et tous dommages matériels.
- Conservez ce Guide de l'Utilisateur dans un endroit qui reste toujours accessible à tous les utilisateurs.
- Respecter les consignes de sécurité sur le lieu de travail et les protocoles de laboratoire, ainsi que les normes en matière de santé, de sécurité et de prévention des accidents.
- En cas d'accident grave, d'endommagement de l'instrument ou si de la fumée ou des flammes apparaissent, coupez immédiatement l'alimentation électrique.
- Pour éteindre entièrement l'instrument de l'alimentation électrique, débranchez le câble d'alimentation.
- Assurez-vous que l'interrupteur principal et la prise du câble d'alimentation de l'instrument soient facilement accessibles.

Niveaux de danger

Les mots d'avertissement sont utilisés pour mettre l'utilisateur en garde contre des situations dangereuses et des dommages matériels. Les mots d'avertissement suivants sont utilisés dans ce Guide de l'Utilisateur.

⚠ AVERTISSEMENT ou **AVERTISSEMENT !** signale une situation dangereuse qui, si elle n'est pas évitée, peut causer la mort ou des blessures graves.

⚠ ATTENTION ou **ATTENTION !** signale une situation dangereuse qui, si elle n'est pas évitée, peut causer des blessures de gravité mineure ou modérée. Il est aussi utilisé pour mettre en garde contre des pratiques dangereuses.

AVIS ou **AVIS** signale des informations jugées importantes mais qui ne concernent pas un danger (p. ex. les messages relatifs à des dommages matériels).

Symboles



AVERTISSEMENT DE SÉCURITÉ : LA DOCUMENTATION DOIT ÊTRE CONSULTÉE DANS TOUS LES CAS OÙ CE SYMBOLE DE SÉCURITÉ EST UTILISÉ SUR L'INSTRUMENT



SURFACE CHAUDE



PIÈCES EN ROTATION



MARCHE (INSTRUMENT ALLUMÉ)



ARRÊT (INSTRUMENT ÉTEINT)



LISEZ LE MANUEL D'UTILISATION AVANT D'UTILISER L'INSTRUMENT



FUSIBLE



DEEE (DÉCHETS D'ÉQUIPEMENTS ÉLECTRIQUES ET ÉLECTRONIQUES)



NUMÉRO DE COMMANDE



NUMÉRO DE MODÈLE



NUMÉRO DE SÉRIE



FABRICANT



DATE DE FABRICATION



MARQUAGE DE CONFORMITÉ EUROPÉENNE



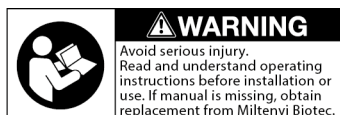
MARQUAGE DE PRODUIT DU ROYAUME-UNI



MARQUE DE CERTIFICATION NRTL : LE PRODUIT RÉPOND AUX NORMES DE SÉCURITÉ CONSENSUELLES IMPOSÉES PAR L'OCCUPATIONAL SAFETY/HEALTH ADMINISTRATION (OSHA), DÉTERMINÉES PAR LES NATIONALLY RECOGNIZED TESTING LABORATORIES (NRTL) TÜV SÜD

Étiquettes de sécurité

Repérez les points dangereux et les symboles de sécurité de l'instrument. Maintenez les étiquettes et les marquages de sécurité propres et lisibles. Contrôlez régulièrement les étiquettes et marquages de sécurité et remplacez ceux qui ne sont pas lisibles ou identifiables à une distance sûre. Contactez Miltenyi Biotec pour obtenir des étiquettes de rechange. L'étiquette de sécurité suivante est apposée à dos de l'instrument et joue un rôle important dans le maintien de la sécurité.



AVERTISSEMENT! Évitez les blessures graves. Lisez et comprenez les instructions d'utilisation avant d'installer ou d'utiliser l'appareil. Si le manuel est manquant, demandez à Miltenyi Biotec de le remplacer.

Les gentleMACS Sleeves comportent une impression de sécurité contrastante. Le marquage de sécurité contrastant signale visuellement la rotation des gentleMACS Sleeves. Le gentleMACS Octo Trough comporte le symbole de sécurité suivant.



Figure 1: Symbole de sécurité sur le gentleMACS Octo Trough et impression de sécurité contrastée sur les gentleMACS Sleeves

- 1 Impression de sécurité contrastée sur les gentleMACS Sleeves
- 2 Symbole de sécurité sur le gentleMACS Octo Trough

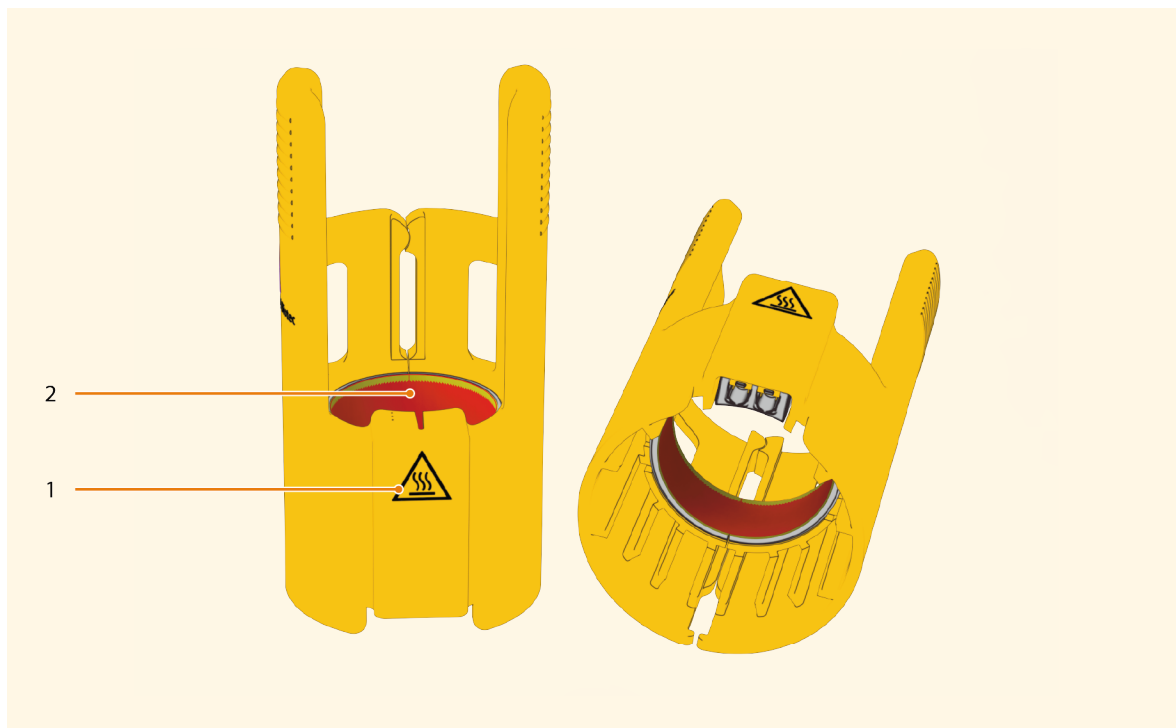


Figure 2: Symbole de sécurité sur les gentleMACS Heaters

- 1 Symbole de sécurité sur les gentleMACS Heaters
- 2 Film chauffant

Dangers électriques

⚠ AVERTISSEMENT

Un choc électrique, un court-circuit, une surchauffe, un incendie ou une explosion peuvent causer des blessures graves ou la mort.

Boîtier de protection

Le boîtier de l'instrument réduit le risque de choc électrique et de court-circuit.

- Ne retirez pas et ne franchissez pas les capots du boîtier.
- Les procédures de maintenance explicitement décrites dans le présent manuel sont les seules exceptions.
- N'utilisez pas l'instrument s'il est ouvert ou démonté.
- N'utilisez pas l'instrument si un objet a pénétré à l'intérieur de l'instrument.
- Avant chaque utilisation, vérifiez que l'instrument ne présente pas de dommages visibles.
- N'utilisez pas l'instrument s'il est tombé ou endommagé.

Câbles et alimentation électrique

L'utilisation de l'instrument avec d'autres câbles que ceux fournis peut être dangereuse.

- Utilisez uniquement le câble d'alimentation fourni.
- N'utilisez pas l'instrument si le câble d'alimentation est endommagé.
- L'instrument a une prise trifilaire dont une troisième fiche pour la mise à la terre.
- Insérer la fiche uniquement dans une prise électrique reliée à la terre. Ne pas essayer d'insérer la fiche dans une prise électrique non reliée à la terre.

- Utilisez l'instrument uniquement avec une source d'alimentation qui est conforme aux spécifications électriques figurant sur la plaque signalétique. Si vous avez des questions sur le type de source d'alimentation à utiliser, contactez le Miltenyi Biotec Technical Support ou votre fournisseur d'électricité local.

Liquides à l'intérieur de l'instrument

Du liquide dans l'instrument peut entraîner des courts-circuits.

- Protégez l'instrument des liquides renversés.
- Ne pas utiliser l'instrument si du liquide s'est répandu à l'intérieur.
- Si du liquide s'est répandu dans l'instrument, le débrancher et contacter le service Miltenyi Biotec Technical Support.
- Nettoyez immédiatement tout liquide renversé.
- Débranchez l'instrument avant de le nettoyer.
- Utilisez uniquement de petites quantités d'agents de nettoyage sur un chiffon doux pour essuyer l'instrument. Ne vaporisez et ne versez pas d'agents de nettoyage sur ou dans l'instrument.

Dangers mécaniques

ATTENTION

Risque d'écrasement.

S'il n'est pas placé sur une surface plane et régulière, l'instrument peut tomber et causer des blessures.

- Placez l'instrument uniquement sur des tables ou des paillasses stables, planes et sans vibrations.
- Manipuler l'instrument avec précaution lors du transport ou repositionnement.

ATTENTION

Risque d'écrasement ou de coupure.

Les bouchons des tubes gentleMACS ont des bords tranchants à l'intérieur. Il existe un risque de blessure par incision en cas de contact avec les bouchons en rotation.

- Utilisez uniquement des tubes rigoureusement fermés et assurez-vous qu'ils sont correctement installés.
- N'installez et ne retirez pas les tubes lorsque les rotors de l'instrument sont en mouvement.

ATTENTION

Risque de pincement des doigts et de happement des cheveux.

Les cheveux peuvent être happés par les rotors lorsque l'instrument est en cours de fonctionnement.

- N'utilisez pas l'instrument sans le gentleMACS Octo Trough, les gentleMACS Sleeves, et le gentleMACS Octo Safety Shield.
- Attacher les cheveux longs.
- Ne touchez pas les rotors lorsque l'instrument est en cours de fonctionnement.

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Dangers biologiques

AVERTISSEMENT

Selon le matériel utilisé, une contamination ou une infection peuvent causer des blessures graves ou la mort.

Matériel biologique

Tous les matériels biologiques doivent être considérés comme potentiellement infectieux.

- Portez des équipements de protection individuelle (tels que des gants, lunettes de protection, etc.) suivant les indications fournies dans la fiche de données de sécurité de la substance en question.
- Utilisez l'instrument dans une hotte de protection si vous manipulez des matériels dangereux ou potentiellement infectieux.
- Décontaminez l'instrument après la manipulation de matériel dangereux ou potentiellement infectieux.
- En cas de dispersion ou de fuite de matériel dangereux ou potentiellement infectieux du système, décontaminez la zone touchée.
- Utilisez un agent de désinfection ou de nettoyage approprié pour l'agent pathogène ou la substance particulière.

Déchets

Tous les déchets liquides et solides doivent être considérés comme dangereux.

- Respecter les réglementations locales relatives à l'élimination des déchets.
- Autoclavez les déchets ou décontaminez-les à l'aide d'un désinfectant approprié.

Dangers chimiques

AVERTISSEMENT

Les substances et les réactifs peuvent être dangereux.

- Toutes les mesures de sécurité indiquées à la rubrique **Dangers biologiques** s'appliquent également à toutes les substances ou tous les réactifs susceptibles d'être présents dans l'échantillon.
- Utilisez l'instrument sous une hotte si des substances et réactifs dangereux sont traités.

Dangers thermiques

ATTENTION

Les surfaces chaudes peuvent provoquer des brûlures.

Lorsque la fonction de chauffage est utilisée, les parties chauffantes des réchauffeurs gentleMACS deviennent brûlantes.

- Ne touchez jamais les parties chauffantes.

Bruit

ATTENTION

Les niveaux sonores élevés peuvent provoquer une déficience auditive.

S'il fonctionne à pleine charge, l'instrument peut produire un bruit fort. Il est recommandé que l'instance responsable mesure ou calcule le niveau de pression acoustique au poste de l'opérateur et en tout point à 1 m autour de l'équipement qui présente le niveau de pression acoustique le plus élevé.

- Le niveau de bruit doit être inférieur à 70 dB.

- Observez les réglementations locales en matière de protection auditive.
- Si l'instrument fonctionne à pleine charge, des équipements de sécurité tels que des écrans acoustiques, des capots ou une protection auditive doivent être utilisés.

Maintenance et transport

Maintenance

Une maintenance ou une réparation inappropriée de l'instrument ou l'utilisation de pièces non autorisées peut provoquer un dysfonctionnement de l'instrument ou l'endommager. Cela peut mettre en danger les utilisateurs.

- Sauf indication contraire dans ce manuel d'utilisation ou dans toute autre documentation fournie par Miltenyi Biotec, ne procédez pas vous-même à l'entretien ou la réparation de l'instrument.
- La maintenance et la réparation doivent être effectuées par du personnel de maintenance Miltenyi Biotec qualifié et certifié.
- Si l'instrument doit être révisé, décontaminez-le pour éliminer toute matière dangereuse.
- Si vous avez des questions sur la décontamination ou l'envoi, veuillez contacter le Miltenyi Biotec Technical Support pour obtenir de l'aide.
- Utilisez uniquement les accessoires et les mises à jour recommandés par Miltenyi Biotec.
- Contactez votre représentant local Miltenyi Biotec pour en savoir plus sur la révision des instruments et les contrats de révision de Miltenyi Biotec, ou consultez le site www.miltenyibiotec.com/support.

Transport

L'instrument doit être transporté avec soin dans l'emballage indiqué par Miltenyi Biotec. Des dommages internes peuvent se produire si l'instrument est soumis à des vibrations excessives ou à une chute. Si l'instrument doit être renvoyé au fabricant pour maintenance, contactez Miltenyi Biotec pour obtenir les instructions et le matériel d'emballage.

Élimination



INFORMATION CLIENT SUR LES DÉCHETS D'ÉQUIPEMENTS ÉLECTRIQUES ET ÉLECTRONIQUES (DEEE)

Éliminez vos produits Miltenyi Biotec en fin de vie conformément à la directive DEEE et à la législation applicable relative à l'élimination des déchets dangereux, qui peut varier en fonction du pays ou de la région. Les équipements électriques peuvent contenir des substances dangereuses susceptibles d'avoir un effet nocif grave sur l'environnement et/ou la santé humaine. Tous les équipements doivent être spécifiquement collectés et traités par des établissements désignés de gestion des déchets et des systèmes qualifiés de conformité à la directive DEEE. En veillant à éliminer vos déchets d'équipements électriques et électroniques en accord avec la directive DEEE et la législation applicable relative à l'élimination des déchets dangereux, vous contribuez à la préservation des ressources naturelles et à la protection de la santé humaine. Miltenyi Biotec s'engage à protéger l'environnement. Miltenyi Biotec propose des programmes de retour des produits en fin de vie dans de nombreux pays, et conclut des partenariats avec des établissements conduisant des systèmes de conformité DEEE agréés dans le monde entier. Miltenyi Biotec reprend et recycle gratuitement vos équipements Miltenyi Biotec en fin de vie. Les conditions et la disponibilité de cette offre varient selon les pays et les différentes exigences réglementaires. Selon le type et l'utilisation de votre équipement, des exigences supplémentaires peuvent s'appliquer. Avant d'expédier l'instrument au fabricant pour élimination, décontaminez-le pour éliminer tout matériel dangereux. Pour de plus amples informations, ou si vous souhaitez éliminer votre équipement Miltenyi Biotec arrivé en fin de vie, veuillez contacter votre représentant Miltenyi Biotec local ou le Miltenyi Biotec Technical Support.

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Istruzioni generali di sicurezza



NEL PRESENTE CAPITOLO SI DESCRIVONO LE SITUAZIONI POTENZIALMENTE PERICOLOSE ASSOCIATE A QUESTO STRUMENTO E SI FORNISCONO INFORMAZIONI IMPORTANTI SULLA SICUREZZA PER RIDURRE AL MINIMO I RISCHI E PROTEGGERE SE STESSI E GLI ALTRI.

Nel presente capitolo si forniscono informazioni importanti per la sicurezza personale e l'uso corretto dello strumento. Leggere e osservare attentamente tutte le istruzioni prima di procedere all'installazione e all'utilizzo dello strumento. Osservare le prassi generali in materia di sicurezza, oltre al presente manuale d'uso.

- Per evitare lesioni personali e danni materiali, utilizzare lo strumento solo come indicato nel presente manuale d'uso.
- Conservare il manuale d'uso in un luogo che sia sempre accessibile a tutti gli utilizzatori.
- Osservare le istruzioni locali per la sicurezza sul posto di lavoro, le prassi di laboratorio locali e le norme in materia di salute, sicurezza e prevenzione degli incidenti.
- In caso di incidenti gravi, danni allo strumento o comparsa di fumo o fiamme, interrompere immediatamente l'alimentazione elettrica.
- Per scollegare completamente lo strumento dall'alimentazione elettrica, staccare il cavo di alimentazione dalla presa.
- Assicurarsi che l'interruttore di alimentazione e la spina del cavo di alimentazione dello strumento siano facilmente accessibili.

Livelli di pericolo

Le indicazioni di avvertenza servono a mettere in guardia su situazioni pericolose e danni materiali. Nel presente manuale d'uso si utilizzano le seguenti indicazioni di avvertenza.

⚠ AVVERTENZA o **AVVERTENZA!** indica una situazione pericolosa che, se non evitata, potrebbe provocare decesso o gravi lesioni.

⚠ ATTENZIONE o **ATTENZIONE!** indica una situazione pericolosa che, se non evitata, potrebbe provocare lesioni di entità minore o moderata. Serve anche a mettere in guardia su pratiche non sicure.

AVVISO o **AVVISO** indica informazioni considerate importanti ma non correlate a pericoli (ad esempio messaggi relativi a danni materiali).

Simboli



AVVERTENZA DI SICUREZZA: CONSULTARE LA DOCUMENTAZIONE IN TUTTI I CASI IN CUI SULLO STRUMENTO COMPARE QUESTO SIMBOLO DI SICUREZZA



SUPERFICIE CALDA



PARTI ROTANTI



ON (ACCESO)



OFF (SPENTO)



LEGGI IL MANUALE D'USO PRIMA DI UTILIZZARE LO STRUMENTO



FUSIBILE



RAEE (RIFIUTI DI APPARECCHIATURE ELETTRICHE ED ELETTRONICHE)



NUMERO D'ORDINE



NUMERO DI IDENTIFICAZIONE



NUMERO DI SERIE



FABBRICANTE



DATA DI FABBRICAZIONE



MARCATURA DI CONFORMITÀ EUROPEA



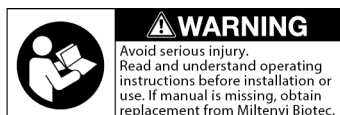
CONFORMITÀ VALUTATA DEL REGNO UNITO



MARCHI DI CERTIFICAZIONE NRTL: IL PRODOTTO È CONFORME ALLE NORME DI SICUREZZA, BASATE SUL CONSENSO, IMPOSTE DALL'AMMINISTRAZIONE DELLA SICUREZZA E DELLA SALUTE SUL LAVORO (OSHA), DETERMINATE DAL LABORATORIO DI PROVA RICONOSCIUTO A LIVELLO NAZIONALE (NRTL) TÜV SÜD

Etichette di sicurezza

Prestare attenzione ai punti pericolosi e ai simboli di sicurezza dello strumento. Mantenere le etichette e i contrassegni sicurezza puliti e leggibili. Controllare regolarmente le etichette e i contrassegni di sicurezza e sostituirli se non sono leggibili o identificabili da una distanza sicura. Contattare Miltenyi Biotec per la sostituzione delle etichette. La seguente etichetta di sicurezza è applicata sul retro dello strumento e svolge un rilevante ruolo nel mantenimento della sicurezza.



ATTENZIONE! Evitare lesioni gravi. Leggere e comprendere le istruzioni per l'uso prima dell'installazione o dell'uso. In caso di mancanza del manuale, richiedere la sostituzione a Miltenyi Biotec.

I gentleMACS Sleeves sono contrassegnati da una stampa di sicurezza a contrasto. La stampa di sicurezza a contrasto rende visibile la rotazione dei gentleMACS Sleeves. Il gentleMACS Octo Trough è contrassegnato dal seguente simbolo di sicurezza.



Figura 1: Simbolo di sicurezza sul gentleMACS Octo Trough e stampa di sicurezza a contrasto sui gentleMACS Sleeves

- 1 Stampa di sicurezza a contrasto sui gentleMACS Sleeves
- 2 Simbolo di sicurezza sul gentleMACS Octo Trough

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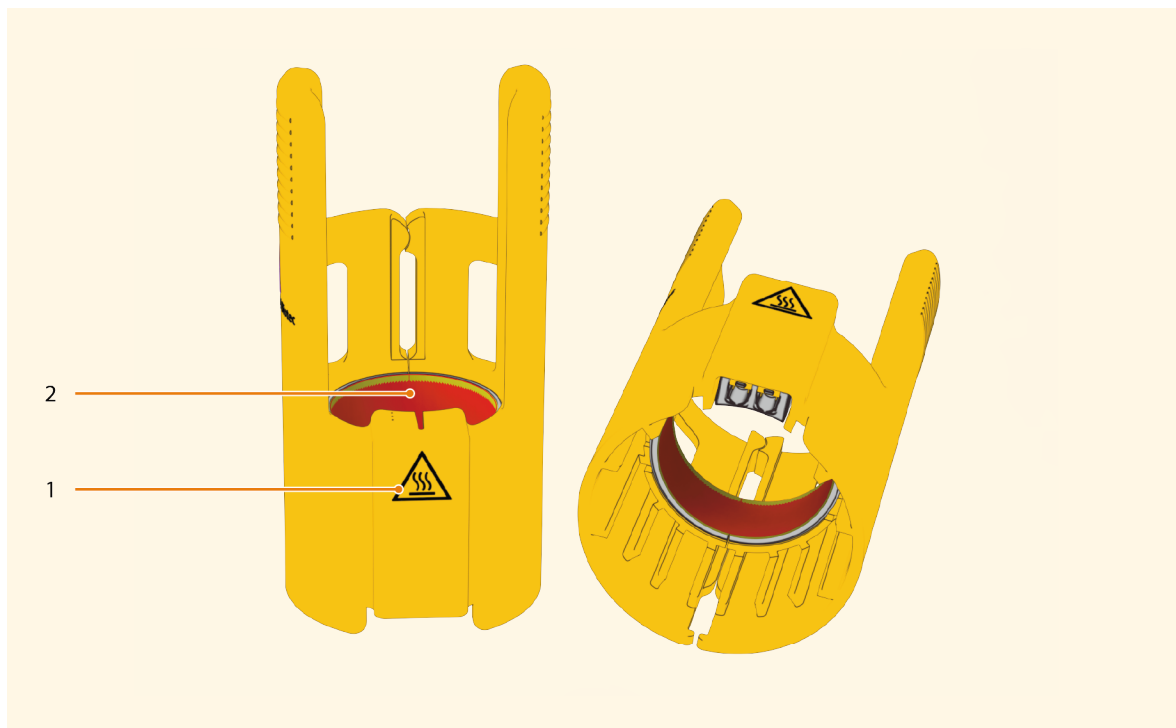


Figure 2: Simbolo di sicurezza sui gentleMACS Heaters

- 1 Foglio riscaldante
- 2 Simbolo di sicurezza sui gentleMACS Heaters

Pericoli elettrici

⚠ AVVERTENZA

Scosse elettriche, cortocircuiti, surriscaldamento, incendi ed esplosioni potrebbero causare morte o gravi lesioni.

Alloggiamento di protezione

L'alloggiamento dello strumento riduce il rischio di scosse elettriche e corto circuiti.

- Non rimuovere né perforare le coperture dell'alloggiamento.
- Fanno eccezione le procedure di manutenzione esplicitamente descritte nel presente manuale.
- Non utilizzare lo strumento se è aperto o smontato.
- Non usare lo strumento se un oggetto è entrato al suo interno.
- Prima di ogni utilizzo, verificare che lo strumento non presenti danni visibili.
- Non usare lo strumento se è caduto o danneggiato.

Cavi e alimentazione elettrica

L'uso dello strumento con cavi diversi da quelli forniti in dotazione è potenzialmente pericoloso.

- Utilizzare esclusivamente il cavo di alimentazione incluso.
- Non utilizzare lo strumento se il cavo di alimentazione è danneggiato.
- Lo strumento è dotato di una spina elettrica a tre contatti, che presenta un terzo pin per la messa a terra.
- Inserire la spina solo in una presa elettrica con messa a terra. Non cercare di inserire la spina in una presa elettrica priva di messa a terra.

- Utilizzare lo strumento solo da una fonte di alimentazione conforme alle specifiche elettriche indicate sulla targhetta. In caso di domande sul tipo di fonte di alimentazione da utilizzare, contattare il Miltenyi Biotec Technical Support o il fornitore di elettricità locale.

Liquidi all'interno dello strumento

I liquidi all'interno dello strumento possono causare corto circuiti.

- Proteggere lo strumento da liquidi versati.
- Non utilizzare lo strumento se sono penetrati liquidi all'interno dello strumento.
- In caso di infiltrazione di liquidi all'interno dell'istrumento, scollegare immediatamente l'istrumento stesso e contattare il Miltenyi Biotec Technical Support.
- Pulire immediatamente i liquidi versati.
- Scollegare lo strumento dall'alimentazione elettrica prima di pulirlo.
- Per pulire lo strumento utilizzare solo piccole quantità di detergente su un panno morbido. Non spruzzare né versare detergenti liquidi sullo strumento o al suo interno.

Pericoli meccanici

ATTENZIONE

Rischio di schiacciamento.

Lo strumento cade se non viene posizionato su una superficie piana e uniforme, con il rischio di lesioni.

- Posizionare lo strumento solo su tavoli o banchi da laboratorio stabili, piani e senza vibrazioni.
- Maneggiare con cura lo strumento durante il trasporto o il riposizionamento.

ATTENZIONE

Rischio di taglio o schiacciamento.

I tappi della provetta gentleMACS Tube hanno bordi taglienti all'interno. Ciò può causare tagli se vengono toccati durante la rotazione.

- Utilizzare solo provette ben chiuse e assicurarsi che siano inserite correttamente.
- Non inserire o rimuovere le provette mentre i rotori dello strumento sono in movimento.

ATTENZIONE

Rischio di intrappolamento di dita e capelli.

I capelli possono essere trascinati dai rotori quando lo strumento è in funzione.

- Non mettere in funzione lo strumento senza il gentleMACS Octo Trough, i gentleMACS Sleeves, e il gentleMACS Octo Safety Shield.
- Legare i capelli lunghi.
- Non toccare i rotori quando lo strumento è in funzione.

Pericoli biologici

AVVERTENZA

La contaminazione o l'infezione potrebbe causare morte o gravi lesioni, a seconda del materiale utilizzato.

Materiale biologico

Tutto il materiale biologico deve essere considerato potenzialmente infetto.

- Indossare dispositivi di protezione individuale (ad esempio guanti, occhiali di sicurezza ecc.) come indicato nella scheda di dati di sicurezza della specifica sostanza.
- Utilizzare lo strumento in una cappa di sicurezza se vengono trattati materiali pericolosi o potenzialmente infettivi.
- Decontaminare lo strumento dopo aver trattato materiale pericoloso o potenzialmente infetto.
- In caso di perdita o fuoriuscita di materiale pericoloso o potenzialmente infetto dal sistema, decontaminare l'area interessata.
- Utilizzare un disinfettante o un detergente appropriato per l'agente patogeno o la sostanza specifica.

Scarti

Tutti gli scarti solidi e liquidi devono essere considerati pericolosi.

- Osservare le norme locali sullo smaltimento dei rifiuti.
- Sterilizzare gli scarti in autoclave o decontaminarli con un apposito disinfettante.

Pericoli chimici

AVVERTENZA

Sostanze e reagenti possono essere pericolosi.

- Tutte le misure di sicurezza riportate nella sezione **Pericoli biologici** valgono anche per le sostanze e i reagenti pericolosi eventualmente presenti nel campione.
- Se si stanno trattando sostanze e reagenti pericolosi utilizzare lo strumento sotto cappa.

Pericoli termici

ATTENZIONE

Le superfici calde possono causare ustioni.

Quando si utilizza la funzione di riscaldamento, il foglio riscaldante dei riscaldatori gentleMACS diventa caldo.

- Non toccare il foglio riscaldante.

Rumore

ATTENZIONE

Livelli di rumore elevati potrebbero provocare danni all'udito.

In caso di funzionamento a carico massimo, lo strumento può produrre un forte rumore. Si raccomanda che l'organismo responsabile misuri o calcoli il livello di pressione sonora nella postazione di lavoro dell'operatore e nel punto a 1 m dall'involucro dell'apparecchiatura che presenta il livello di pressione sonora più elevato.

- Il livello di rumore consigliato dovrebbe essere inferiore a 70 dB.
- Osservare le norme locali in materia di protezione dell'udito.

- Se si utilizza lo strumento con il massimo carico, è necessario utilizzare dispositivi di sicurezza protettivi come baffles fonoassorbenti o cappe per la riduzione del rumore o protezioni per le orecchie.

Manutenzione e trasporto

Interventi di manutenzione

Interventi di manutenzione o riparazione impropri sullo strumento o l'uso di parti non autorizzate possono causare malfunzionamento o danni allo strumento. Ciò può comportare pericoli per gli utilizzatori.

- Salvo quanto altrimenti specificato nel presente manuale d'uso o in altra documentazione di Miltenyi Biotec, la manutenzione o la riparazione dello strumento da soli.
- Gli interventi di manutenzione e riparazione devono essere eseguiti da personale di servizio Miltenyi Biotec certificato e qualificato.
- Se lo strumento necessita di un intervento di manutenzione, decontaminarlo per rimuovere eventuali materiali pericolosi.
- In caso di domande relative a una decontaminazione o a una spedizione corrette, contattare il Miltenyi Biotec Technical Support per ricevere assistenza.
- Utilizzare esclusivamente accessori e aggiornamenti raccomandati da Miltenyi Biotec.
- Per informazioni sull'assistenza estesa e sui contratti di assistenza di Miltenyi Biotec relativi allo strumento, rivolgersi al rappresentante Miltenyi Biotec di zona o visitare la pagina www.miltenyibiotec.com/support.

Trasporto

Lo strumento deve essere trasportato con cura nell'imballaggio specificato da Miltenyi Biotec. Danni interni potrebbero verificarsi se lo strumento è soggetto a vibrazioni eccessive o viene fatto cadere. Se lo strumento deve essere rispedito al fabbricante per assistenza, contattare Miltenyi Biotec per istruzioni e materiali di imballaggio.

Smaltimento



INFORMAZIONE PER L'UTILIZZATORE SUI RIFIUTI DI APPARECCHIATURE ELETTRICHE ED ELETTRONICHE (RAEE)
Smaltire i prodotti Miltenyi Biotec al termine del ciclo vita conformemente alla legislazione applicabile in materia di smaltimento dei RAEE e dei rifiuti pericolosi, che può variare da regione a regione e da Paese a Paese. Le apparecchiature elettriche possono contenere sostanze pericolose che a loro volta possono avere un grave effetto deleterio sull'ambiente e/o sulla salute dell'uomo. Tutte le apparecchiature devono essere raccolte e trattate in maniera specifica dagli appositi impianti per la gestione dei rifiuti e tramite piani di conformità RAEE qualificati. Provvedendo a smaltire le apparecchiature elettriche ed elettroniche non più necessarie secondo la legislazione applicabile in materia di RAEE e rifiuti pericolosi, si contribuisce a preservare le risorse naturali e a proteggere la salute dell'uomo. Miltenyi Biotec si impegna a proteggere l'ambiente. Miltenyi Biotec offre in molti Paesi programmi per la restituzione dei prodotti al termine del ciclo vita e collabora in tutto il mondo con piani di conformità RAEE autorizzati. Miltenyi Biotec accetta gratuitamente la restituzione delle apparecchiature Miltenyi Biotec al termine del ciclo vita per avviarle al riciclo. I termini e la disponibilità di questa offerta variano in base all'area geografica a causa delle differenze nei requisiti regolatori. Si noti che, a seconda del tipo di apparecchiatura e del suo impiego, possono valere requisiti aggiuntivi. Prima di spedire lo strumento al fabbricante per lo smaltimento, decontaminare lo strumento per rimuovere eventuale materiale pericoloso. Per ulteriori informazioni o se si desidera smaltire le apparecchiature Miltenyi Biotec al termine del ciclo vita, contattare il rappresentante locale Miltenyi Biotec oppure il Miltenyi Biotec Technical Support.

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1.1 Intended use

The gentleMACS Octo Dissociator with Heaters is a benchtop instrument for fully automated and standardized tissue dissociation, perfusion or homogenization of up to eight samples. Equipped with eight individual heating units and numerous optimized and ready-to-use gentleMACS Programs, the gentleMACS Octo Dissociator with Heaters offers a fully automated workflow for tissue dissociation, perfusion, and homogenization. The gentleMACS Octo Dissociator with Heaters is for research-use only in a laboratory environment. It is to be used by laboratory professional users only.

1.2 Instrument schematics

- | | | | |
|---|--|----|---|
| 1 | gentleMACS Safety Shield, referred to as Safety Shield | 7 | gentleMACS Sleeve, referred to as Sleeve |
| 2 | Touchscreen | 8 | LAN port |
| 3 | Power switch | 9 | CAN port |
| 4 | Power port | 10 | Type label |
| 5 | USB port | 11 | gentleMACS Octo Trough, referred to as Trough |
| 6 | 2D barcode reader | | |

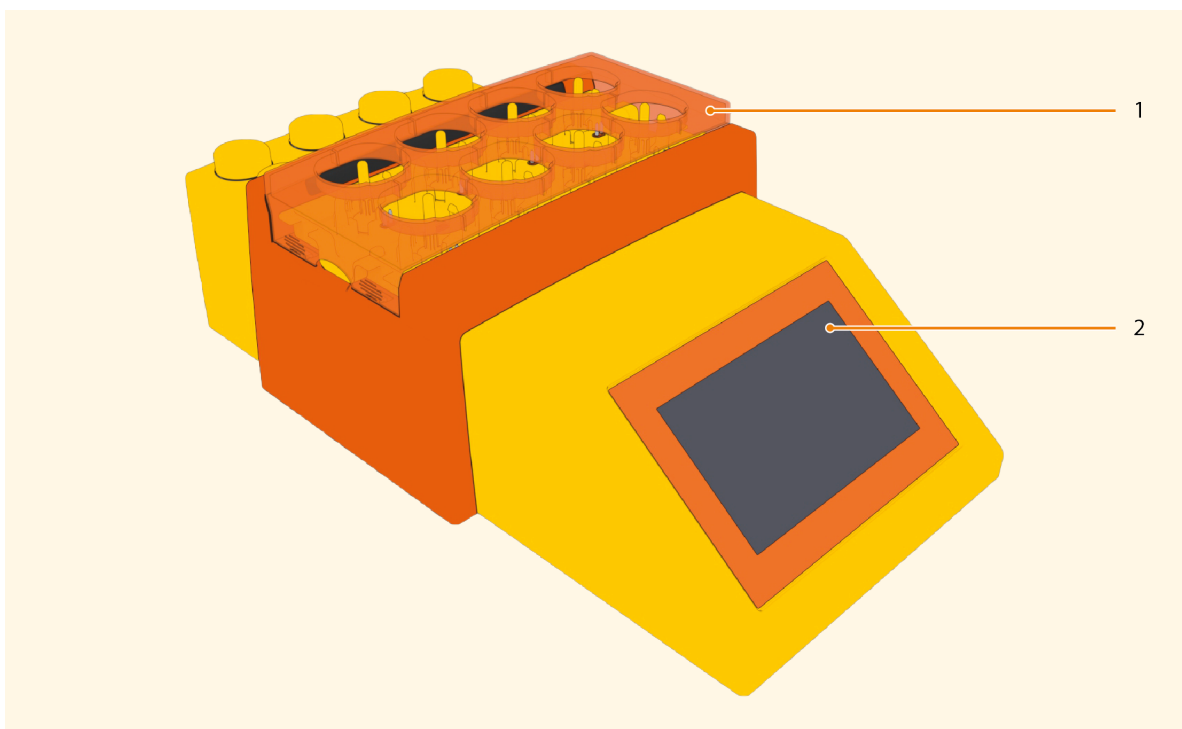


Figure 1.1: Front view of the gentleMACS Octo Dissociator with Heaters

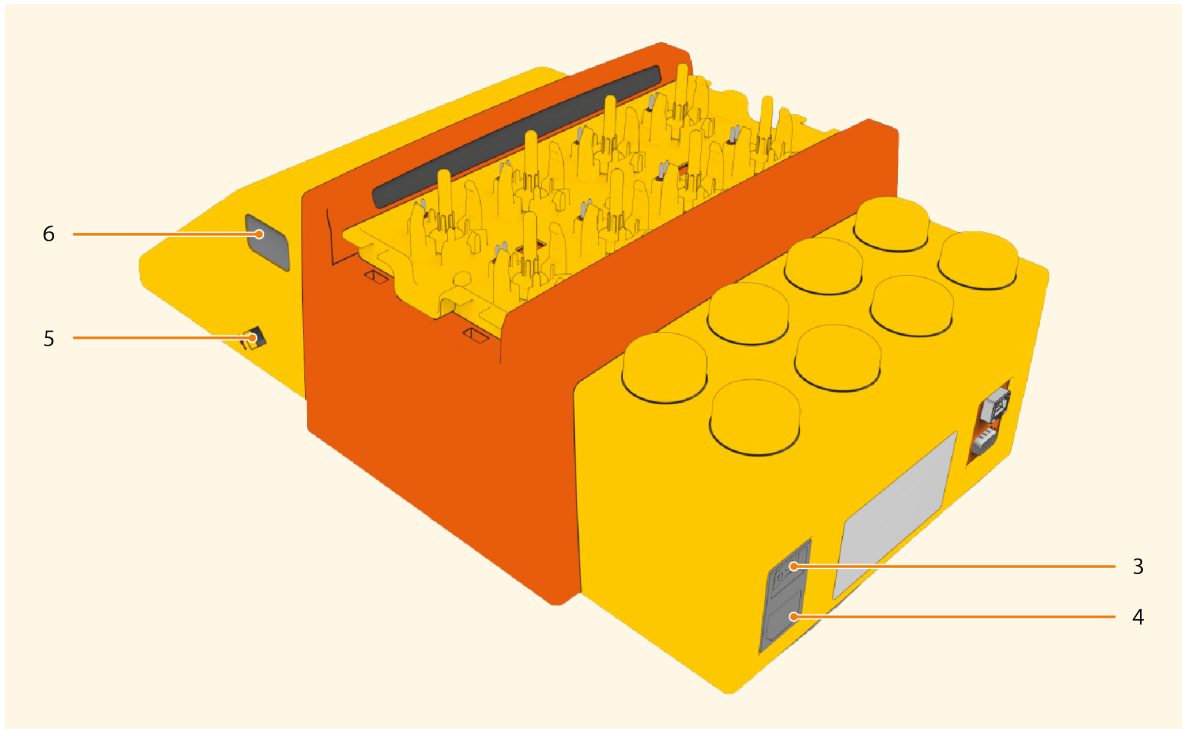


Figure 1.2: Rear view of the gentleMACS Octo Dissociator with Heaters, Safety Shield removed

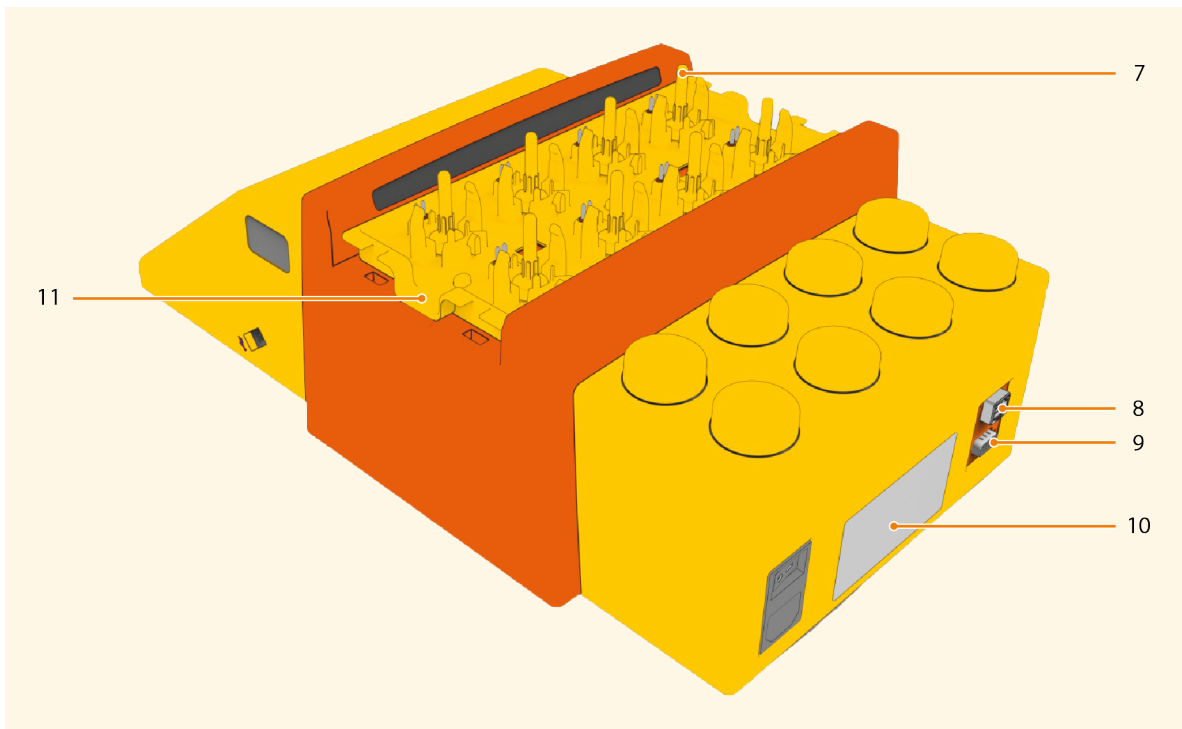


Figure 1.3: Rear view of the gentleMACS Octo Dissociator with Heaters, Safety Shield removed

1.3 Sample preparation

The gentleMACS Octo Dissociator with Heaters provides the solution for the preparation of single-cell, or single-nuclei suspensions, and homogenates from a wide range of tissues. Samples are processed using gentleMACS Tubes, which have caps with specially designed rotors and stators.

The gentleMACS Octo Dissociator with Heaters provides:

- the preparation of viable single-cell suspensions by mechanical and enzymatic dissociation, including incubations at 37 °C and in combination with the gentleMACS Octo Coolers also between +2°C to +8°C,
- the preparation of intact nuclei suspension by mechanical disruption at low temperature in combination with the gentleMACS Octo Coolers (+2°C to +8 °C),
- the preparation of thorough tissue homogenates for subsequent extraction of sub-cellular material, such as total RNA, DNA, proteins, organelles, and pathogens,
- the *ex vivo* perfusion of resected rodent organs, such as liver and heart, using the gentleMACS Perfusion Technology,
- simultaneous or independent processing of up to eight samples, even using different programs,
- easy access to predefined gentleMACS Programs which are optimized for particular applications,
- the option to create user-defined programs.

1.4 gentleMACS Tubes

gentleMACS Tubes consist of a stator and rotor element that provides the exact sheer forces necessary to gently pull cells from tissues or intact molecules from cells. A specially engineered tube enclosure always directs the sample flow towards the rotor and stator element. This sophisticated design results in highly efficient tissue dissociation and homogenization using C Tubes and M Tubes.

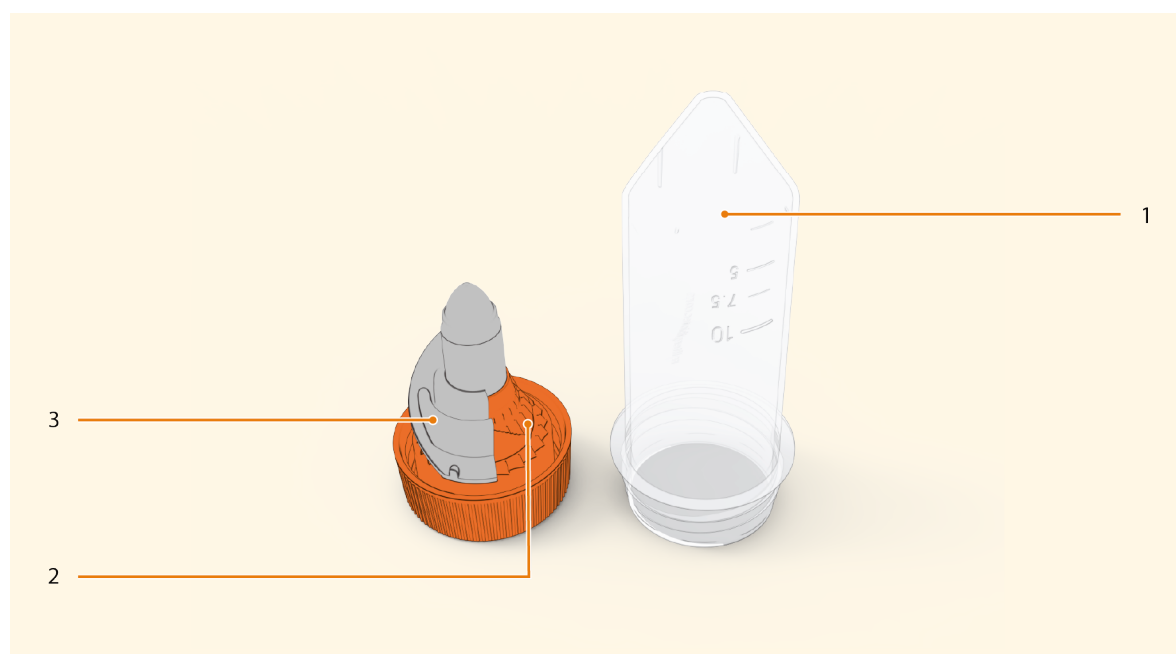


Figure 1.4: Cap of the gentleMACS Tubes (exemplary)

1 Tube enclosure

3 Rotor

2 Stator

Two dedicated types of gentleMACS Tubes have been designed for the preparation of samples for cell biology or molecular biology applications:

- Purple C Tubes are designed for the gentle preparation of single-cell, or single-nuclei suspensions from tissues for subsequent cell separation, cell analysis, cell culture, or genomic analysis, respectively.
- Orange M Tubes are designed for the homogenization of tissues and cells for subsequent subcellular or molecular analysis.

gentleMACS Tubes are suitable for:

- the processing of sample volumes from 500 μ L to 10 mL and from 20 mg to 4,000 mg of tissue in a single tube,
- sterile sample handling.

1.5 gentleMACS Heaters

For combined enzymatic and mechanical dissociation processes the instrument is equipped with gentleMACS Heaters for each of the eight tube positions. The gentleMACS Heaters allow to apply 37 °C either to all eight positions or individually to each tube. By gently pressing the clamps, the gentleMACS Heaters can be easily attached to the tube positions, thus connecting the gentleMACS Heaters to the instrument via its electrical contact pins.

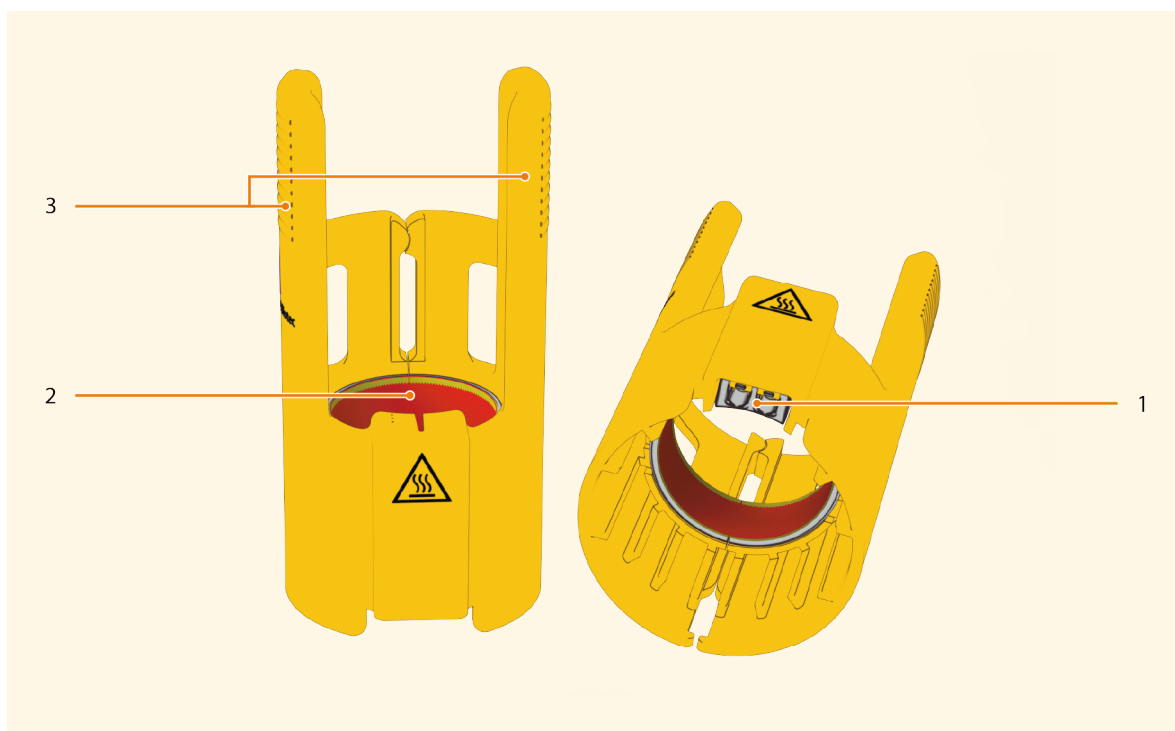


Figure 1.5: The gentleMACS Heaters for incubation of samples at 37 °C

1 Electrical contacts

3 Clamps

2 Heating foil

1.6 Perfusion Technology

The gentleMACS Perfusers are designed for the gentleMACS Perfusion Technology and are used in combination with the gentleMACS Perfusion Sleeves and the gentleMACS Octo Dissociator with Heaters. They are single-use consumables that enable *ex vivo* perfusion of tissues. During the perfusion process, enzymes digest the tissue. Subsequent processing of the tissue with C Tubes results in a single-cell suspension which can be used for a wide variety of different downstream applications, such as cell separation, cell culture, cell or molecular analysis.

1.7 gentleMACS Octo Coolers

The gentleMACS Octo Coolers are an accessory for gentleMACS Octo Dissociators. They are designed to maintain the temperature of samples inside the tubes between +2°C to +8 °C during cold dissociation or homogenization. The coolers are compatible with all types of gentleMACS Tubes or gentleMACS Perfusers.

1.8 MACS Tissue Dissociation Kits

A broad selection of MACS Tissue Dissociation Kits, including predefined enzyme mixes, provide convenient and reproducible tissue dissociation using the gentleMACS Octo Dissociator with Heaters. A comprehensive list of MACS Tissue Dissociation Kits for numerous applications is available for download at www.miltenyi.com/epitopes.

1.9 Predefined tissue dissociation and homogenization programs

More than 80 preset gentleMACS Programs have been specifically developed to offer standardized procedures for tissue dissociation in virtually any research field. A comprehensive list of optimized gentleMACS Programs and detailed gentleMACS Protocols for numerous applications are available for download at www.miltenyi.com/brochureapps.

1.10 Customized dissociation programs

In addition to the ready-to-use gentleMACS Programs optimized for specific applications, the gentleMACS Octo Dissociator with Heaters also allows users to create new programs. See **Creating a new program on page 63**.

2

Installation

Unpack the instrument carefully and confirm that all components have been successfully delivered without damage that may have occurred during transportation.

WARNING! If there is any damage, do not use the instrument. Contact your local Miltenyi Biotec representative or Miltenyi Biotec Technical Support. Operating a damaged instrument may cause mechanical hazards, optical radiation hazards, fire hazards, or electric shock. Read the chapter Important safety information before installing and assembling the instrument.

Retain the original packaging material.

2.1 Components included in the delivery

The following components are included in the delivery of the gentleMACS Octo Dissociator with Heaters (# 130-134-029):

- 1× gentleMACS Octo Dissociator with Heaters
- 8× gentleMACS Heaters
- 1× Power cable
- 1× User manual

2.2 Requirements

Meet the following requirements to install the instrument:

- The instrument requires a power supply.
- Place the instrument on a flat and clean surface of the dimensions 495 mm × 285 mm plus at least 15 cm on all sides to ensure for sufficient air circulation.
- The display and top of the instrument must be accessible.
- The instrument must be operated in a safety hood if hazardous or unknown materials are being processed.
- Do not place the instrument near radiators, heat registers, stoves, or other equipment (including amplifiers) that generate heat.
- Protect the instrument from direct sunlight.

2.3 Installation

To install the gentleMACS Octo Dissociator with Heaters:

- 1 Carefully remove the device from the cardboard box.

CAUTION! The instrument could fall down and cause serious injury to hand or foot. Place the instrument only onto stable, even, and vibration free tables or laboratory benches.

- 2 Place the instrument on a secure, clean, and stable workbench that can support its weight and size.
- 3 Plug the instrument into an electrical outlet.
- 4 Set the switch located above the plug socket to ON ("I" indicates "ON", "O" indicates "OFF").

The instrument performs a start-up check that runs for a few seconds.

3

Required materials

3.1 Disposables

The materials listed in **Table 3.1** are compatible with the gentleMACS Octo Dissociator with Heaters.

Product	Description	Capacity	Order no.
gentleMACS C Tubes	For gentle preparation of - single-cell suspensions from tissues for subsequent cell separation, cell analysis, and cell culture. - intact nuclei suspension for genomic analysis.	25 tubes, sterile, single-packed	130-093-237
		100 tubes, sterile, packed as 4x25 tubes	130-096-334
gentleMACS M Tubes	For homogenization of tissues and cells for subsequent subcellular and molecular analysis.	25 tubes, sterile, single-packed	130-093-236
		100 tubes, sterile, packed as 4x25 tubes	130-096-335
M Tubes with Strainer	For homogenization of tissues and cells for subsequent subcellular and molecular analysis. The strainer removes aggregates or large particles from the sample.	50 tubes, sterile, packed as 2x25 tubes (strainer: 600 µm mesh)	130-094-392
gentleMACS Perfusers	For <i>ex vivo</i> perfusion of tissues, in combination with the gentleMACS Perfusion Sleeves.	25 tubes, sterile, single-packed	130-128-151
gentleMACS Perfusers 2	For <i>ex vivo</i> perfusion of smaller tissues, in combination with the gentleMACS Perfusion Sleeves.	25 tubes, sterile, single-packed	130-134-803

Table 3.1: Disposables compatible with the gentleMACS Octo Dissociator with Heaters

3.1.1 Additional disposables

MACS SmartStrainers are filters that are designed for the removal of cell aggregates or large particles after tissue dissociation. The MACS SmartStrainers are available with three mesh sizes:

- 30 µm (50 pieces # 130-098-458, 4×25 pieces # 130-110-915),
- 70 µm (50 pieces # 130-098-462, 4×25 pieces # 130-110-916),
- 100 µm (50 pieces # 130-098-463, 4×25 pieces # 130-110-917).

They fit into standard 15 and 50 mL conical tubes of all major suppliers.

MACS Tissue Dissociation Kits were designed for the convenient and standardized enzymatic dissociation of multiple tissues in combination with the gentleMACS Octo Dissociator with Heaters. For a comprehensive list of MACS Tissue Dissociation Kits, see www.miltenyi.com/epitopes.

3.2 Accessories

Product	Description	Order no.
gentleMACS Octo Coolers (4×)	For protocols with a cooling step	130-130-533
gentleMACS Perfusion Sleeves (sterile, packed as 2×2 pieces)	Adapters for attaching gentleMACS Perfusers and gentleMACS Perfusers 2	130-128-752

Table 3.2: Accessories for the gentleMACS Octo Dissociator with Heaters

3.3 Spare parts

Product	Description	Order no.
gentleMACS Sleeves (2×)	Adapters for attaching gentleMACS Tubes	130-093-464
gentleMACS Heater	Heating unit	130-105-228
gentleMACS Octo Cooler (1×)	For protocols with a cooling step	130-131-248
gentleMACS Octo Trough	Safety container for spilled liquid	130-136-426
gentleMACS Octo Safety Shield	Safety shield for protection	130-096-542

Table 3.3: Spare parts of the gentleMACS Octo Dissociator with Heaters

Only use spare parts and accessories recommended by Miltenyi Biotec. Failure to use recommended spare parts and disposables may compromise safe operation and may result in inaccurate results and reduced lifetime of the instrument. Miltenyi Biotec does not honor any warranty or accept any responsibility for damages resulting from the use of inappropriate accessories.

4

Instrument operation

4.1 Switching on

Switch on the instrument with the power switch on the rear side of the instrument (**Figure 1.2**).

The instrument starts and the software opens. The internal fan automatically starts operating and reduces its speed after a few seconds.

After the first start of the instrument, naming the instrument and setting date and time is required. This information can be edited. See **Editing instrument name on page 66** and **Editing date and time on page 67**.

4.2 Switching off

- 1 Shut down the software before switching off the instrument. Tap the shut down button in the top indicator bar (**Figure 4.1**).
- 2 Tap **Shutdown** in the message window to proceed.
The software shuts down.
- 3 Switch off the instrument with the power switch on the rear side of the instrument (**Figure 1.2**).

4.3 The user interface

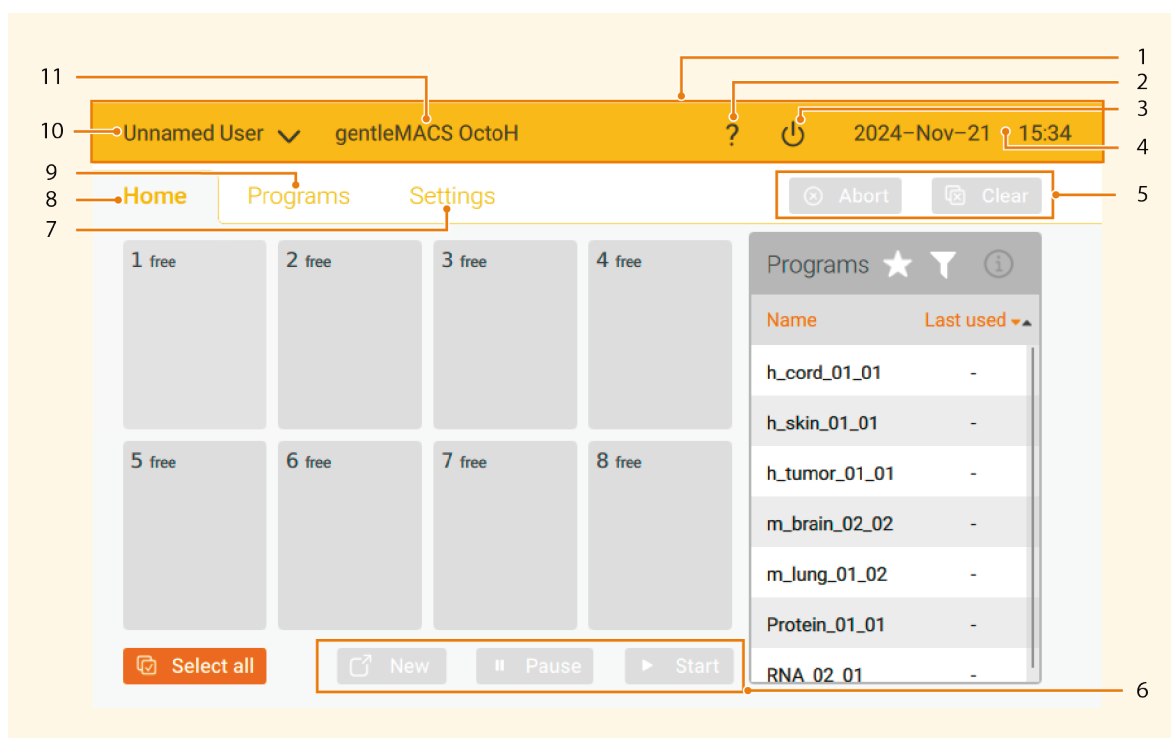


Figure 4.1: Overview of the user interface

1	Top indicator bar	Shows name of current user, instrument name, date and time; includes the help button and shut down button
2	Help button	Opens the help information on the instrument
3	Shut down button	Button to shut down the software before switching off the instrument
4	Date and time	Current date and time set on the instrument
5	Local position buttons	Buttons controlling the functions Abort , and Clear for all selected positions
6	Global position buttons	Buttons controlling the functions New , Pause and Start for all positions in the corresponding status
7	Home hub	Menu hub with instrument position overview and Programs list; gives an overview of the status of each position and is the starting point for assigning programs to positions and controlling sample runs
8	Programs hub	Menu hub for managing programs, including the program editor
9	Settings hub	Menu hub for managing instrument and user settings
10	User	Shows the current user of the instrument, users can be switched in the dropdown list
11	Instrument name	Name of the instrument

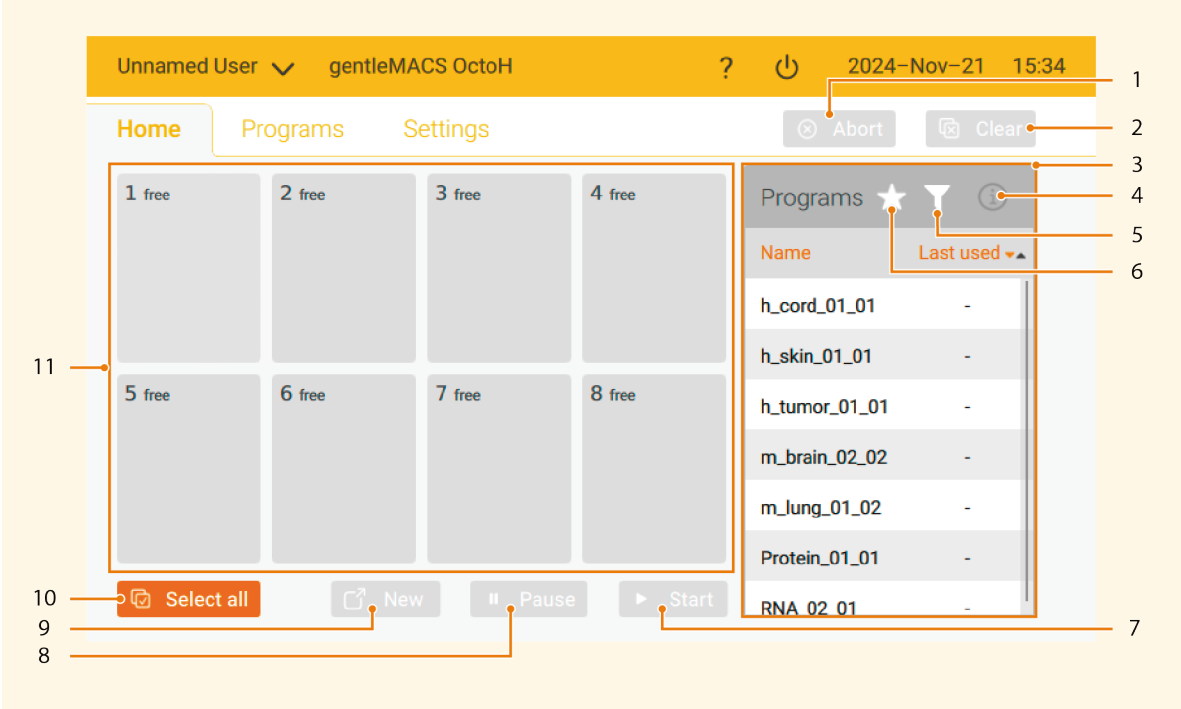


Figure 4.2: Overview Home hub

1	Abort button	Aborts run of the selected position boxes
2	Clear button	Clears the assigned programs or Done status of the selected position boxes
3	Programs list	List of programs available
4	Program details button	Shows information about the selected program like tube type needed, duration, rotations per run, species, starting material etc.; option to mark selected program as Favorite
5	Filter button	Opens Filter attribute window; option to filter by tube type, thermal condition, species, starting material, program author and favorite
6	Favorites button	Filters for favorite programs of the logged-in user
7	Start button	Starts runs on all positions in the status Ready
8	Pause button	Pauses all active sample runs
9	New button	Clears the assigned programs of all position boxes that are not running or paused
10	Select all/ Deselect all button	Selects or deselect all position boxes at once. If all position boxes are selected, the Select all button turns into a Deselect all button.
11	Position boxes	Managing the runs on the eight instrument positions; shows status of each position (see Status of position boxes on the next page)

4.4.1 Status of position boxes

Status	Color	Description
free	Gray	No tube inserted, no program assigned. The position is free to use.
selected	Gray with orange border	The position is selected.
partly	Green, pulsing	Position is partly ready. A program is assigned to the position box, but a tube and/or heater is still needed, indicated by the icon in the upper right corner of the position box. Or a tube and/or heater are placed but no program is assigned to the position box.
ready	Green	The position is ready. A tube and/or heater is inserted and a program is assigned.
running	Blue	A program is running on the position. The progress bar and timer display the remaining time to complete the program.
paused	Blue, pulsing	The current running program on the position is paused.
break	Blue, pulsing	The current running program on the position has reached a break state. To resume the program, tap the local Start button in the position box and tap Resume in the pop-up window.
done	Gray	The program is finished. The position details button shows the elapsed time since completion of the program. The position box status changes to Done also after a run is aborted.
error	Red	An error occurred. See Troubleshooting table on page 77 .

Table 4.1: Overview of position box statuses

4.5 Programs hub

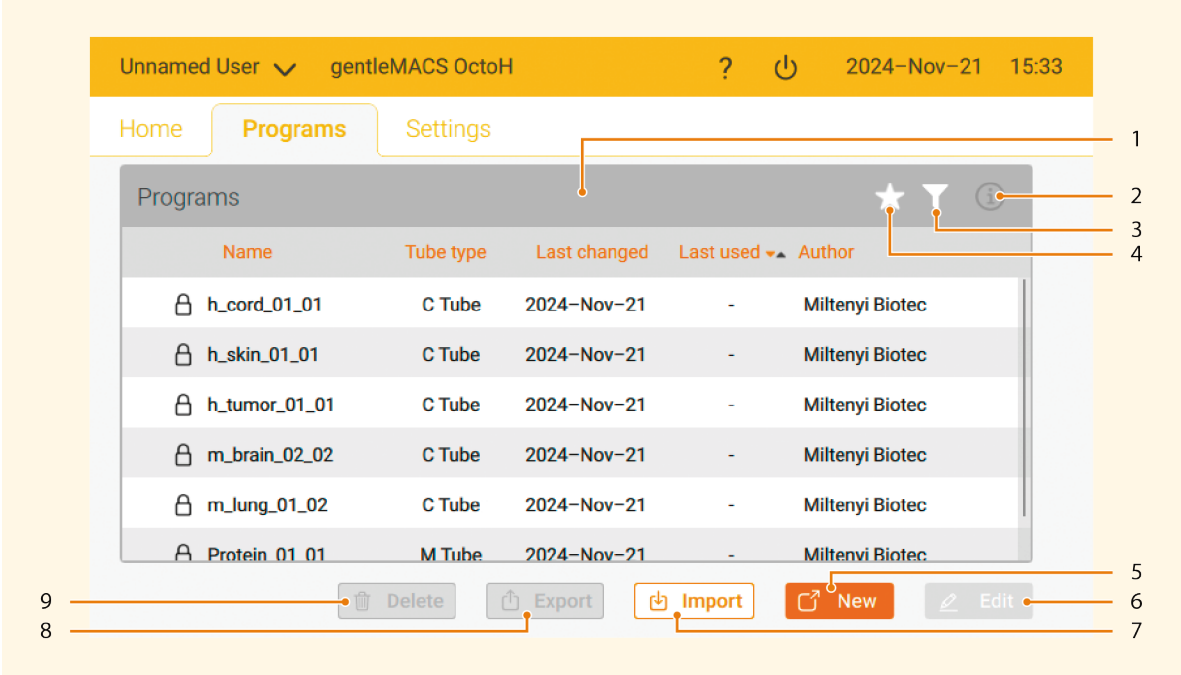


Figure 4.3: Overview Programs hub

- | | | |
|---|------------------------|---|
| 1 | Programs list | List of programs available. The padlock icon indicates which programs can be edited or deleted.
Programs can be sorted by Name, Tube type, Last changed, Last used, and Author by tapping the row heading. |
| 2 | Program details button | Shows information about the selected program like tube type needed, duration, total rotations per run, species, starting material etc.;
option to mark selected program as Favorite . |
| 3 | Filter button | Opens filter attribute window with the option to filter by tube type, thermal condition, species, starting material, program author, and favorite. |
| 4 | Favorites button | Filters for favorite programs of the current user. |
| 5 | New button | Create new program. Opens the program editor window. |
| 6 | Edit button | Edit selected program. Opens the program editor window. Only user programs can be edited. |
| 7 | Import button | Imports selected program from the USB flash drive. |
| 8 | Export button | Exports selected program to USB flash drive. |
| 9 | Delete button | Delete selected program. Only custom programs can be deleted. |

4.5.1 Creating a new program

Do not exceed 3,200 rotations per run, otherwise the gentleMACS Tubes might get damaged.

- 1 Tap **New** in the **Programs** hub. The program editor window opens.
- 2 Enter a name for the new program.
- 3 Tap on the plus symbol to insert a new command. The position where a further command is inserted can be changed using the arrow buttons.
- 4 Add and define all commands needed.
- 5 If needed, commands can be changed, deleted, or rearranged.
Change the position to insert a further command using the arrow buttons if needed.

- 6 Tap **Edit filter** to add filter parameters for the program. At least the tube type needed to run the program has to be defined.
- 7 Tap **Save** to save the new program.
- 8 To return to the **Programs** list, tap the back button next to the program name.

Program commands

Command	Description
Spin	Defines the speed, direction, and duration of rotation in seconds. Speed is defined as revolutions per minute (rpm). The change of velocity must not exceed 6,000 rpm per second.
Heater	Defines if heaters are turned on or off. Add a command to turn heaters on and another to turn heaters off. The temperature of the heaters is set to 37 °C and can not be changed.
Loop	Adds start and end of a loop to the program. Commands between the start and end loop commands are repeatedly executed for the defined numbers of cycles.
Ramp	Defines the time in seconds required to reach a certain speed in rpm. If a program starts with a ramp command, the starting speed will be 0 rpm. If a ramp command is added after a spin command, the starting speed will be from the rpm of the spin command.
No spin	Defines duration in seconds of a step without spinning
Incubate	Defines the duration in minutes of the incubation step with a slow spinning of 20 rpm counterclockwise
Break	Adds a break command. The program will pause in a break state until the user resumes the program.

Table 4.2: Overview of program commands for custom programs

4.5.2 Editing a program

Only custom programs can be edited or deleted. Custom programs do not show the padlock symbol.

- 1 Open the **Programs** hub.
- 2 Tap on the program to be edited.
- 3 Tap **Edit**. The program editor windows opens.
- 4 Edit the program. You can change the program name. Commands can be changed, deleted or rearranged. To change the order of commands, tap on the respective command to select it and change position with the arrow buttons.
- 5 Tap **Edit filter** to change filter parameters for the program. At least the tube type needed to run the program has to be defined.
- 6 Tap **Save** to save the changed program.

4.5.3 Filtering programs

The system combines multiple filter attributes. Attributes of the same category are combined with the filter requirement "or", attributes from different categories are combined with the filter requirement "and".

Users can filter the **Programs** list for programs with certain attributes.

- 1 Tap on the filter button in the **Home** hub or **Programs** hub to open the **Filter** window.

- 2 Select all the attributes that the program should have. Filter attributes are:
 - tube type,
 - thermal condition,
 - species,
 - starting material,
 - author, and
 - favorite.
- 3 Tap X to close the **Filter** window. The **Programs** list shows only programs with the selected attributes.

4.5.4 Deselecting program filters

To remove the filter applied to the program list, perform the following steps:

- 1 Tap on the filter button in the **Home** hub or **Programs** hub to open the **Filter** window.
- 2 Tap **Deselect all**.
- 3 Tap X to close the **Filter** window.

4.5.5 Deleting programs

Only custom programs can be edited or deleted.

Assigned programs can not be deleted. Miltenyi Programs can not be deleted.

- 1 Open the **Programs** hub.
- 2 Tap on the program to be deleted in the programs list.
- 3 Tap **Delete**.
- 4 Confirm the deletion of the selected program.

4.5.6 Exporting programs

You can export programs to a USB flash drive and transfer them to another gentleMACS instrument. Programs are exported as bundles containing one or several programs. Make sure that the USB flash drive is formatted as exFAT for compatibility with the operating system. If required, change the format on a PC.

- 1 Insert the USB flash drive to the USB port of the gentleMACS Octo Dissociator with Heaters.
- 2 Go to the **Programs** hub.
- 3 Tap on the program to export.
To select several programs for export, tap and hold on the first program and then select all other programs to be exported.
- 4 Tap **Export**.
- 5 Choose the target folder on the USB flash drive to export the program to.
- 6 Confirm to resume the export to the USB flash drive.
- 7 After the export is finished, remove the USB flash drive from the instrument.

4.5.7 Importing programs

Use this function to import programs from a USB flash drive to transfer them to another gentleMACS instrument, or to update the Miltenyi Biotec program database with new Miltenyi Biotec programs. Only programs which are supplied by Miltenyi Biotec, with Miltenyi Biotec as specified author, are permitted for

import. Programs are imported as bundles containing one or several programs. Make sure that the USB flash drive is formatted as exFAT for compatibility with the operating system. If required, change the format on a PC.

- 1 Insert the USB flash drive to the USB port of the gentleMACS Octo Dissociator with Heaters.
- 2 Go to the **Programs** hub.
- 3 Tap **Import**.
- 4 Choose the program bundles to be imported from the USB flash drive.
- 5 Confirm to resume the import from the USB flash drive.
- 6 After the import is finished, remove the USB flash drive from the instrument.

4.6 Settings hub

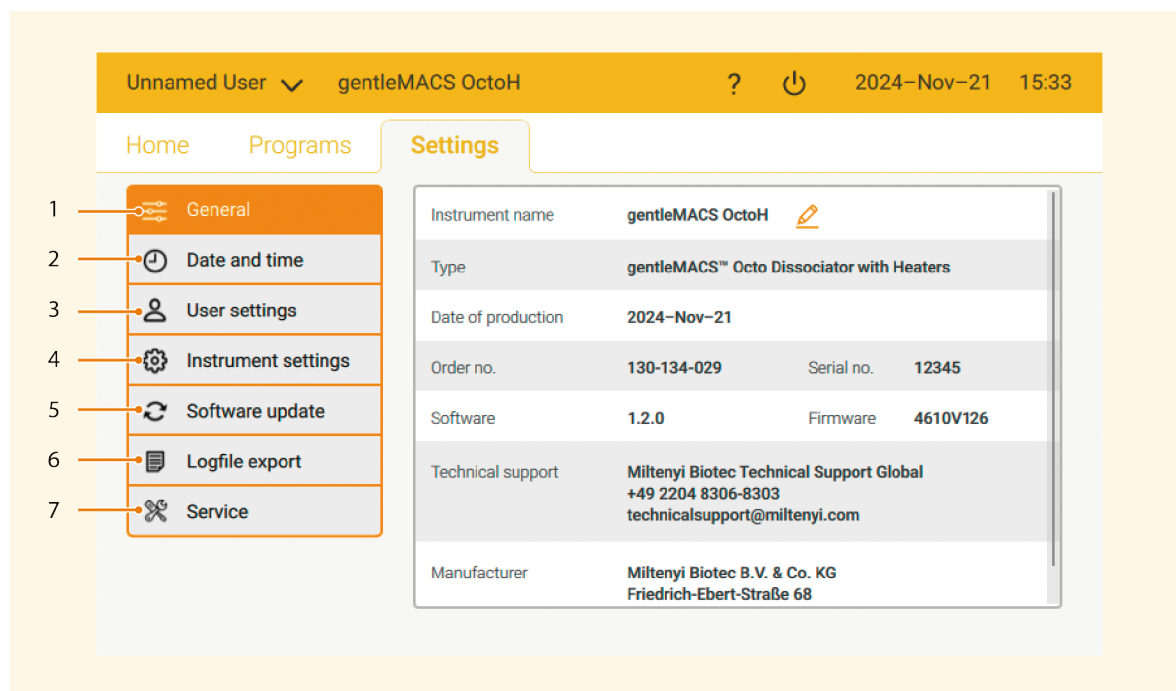


Figure 4.4: Overview Settings hub

- | | | |
|---|--------------------------------|--|
| 1 | General tab | General information about the instrument; tap the pen icon to change the instrument name |
| 2 | Date and time tab | Set date and time |
| 3 | User settings tab | Overview of all user profiles on this instrument, option to switch users, delete, clone, or edit user profiles, and to add new user profiles |
| 4 | Instrument settings tab | Settings for notifications, LED feedback, and display brightness |
| 5 | Software update tab | Check and update the software version |
| 6 | Logfile export tab | Export log files to a USB flash drive, see Exporting log files on page 78 |
| 7 | Service tab | Access to service mode for authorized service personnel |

4.6.1 Editing instrument name

- 1 Go to **Settings > General**.
- 2 Tap on the pen symbol next to the instrument name.
- 3 Edit the instrument name.
- 4 Confirm the changes.

4.6.2 Editing date and time

- 1 Go to **Settings > Date and time**.
- 2 Tap on the number to be changed. The selected numbers turn orange.
- 3 Edit date and time.
- 4 To confirm the changes, tap **Apply**.

4.6.3 User settings

Settings for notifications and brightness, favorite programs and the date of last use of programs by a user are saved in the profile of the signed-in user. User profiles help the different users to access their frequently used programs easier.

Adding new user profiles

- 1 Go to **Settings > User settings**.
- 2 Tap **New**.
- 3 Enter the user profile name.
- 4 To confirm, tap enter.
The new user profile is now included in the user profile list.

Switching user profiles

To switch between user profiles, do one of the following:

- Tap on the user name in the upper left corner of the top indicator bar and select the user profile to use.
- Go to **Settings > User settings** and select the user profile to use. Tap **Switch** to change the user profiles. The person icon indicates the currently active user.

Editing user profile names

- 1 Go to **Settings > User settings**.
- 2 Tap on the user profile to be edited.
The selected user profile is shown in orange.
- 3 Tap **Edit**.
- 4 Change the user profile name.
- 5 To confirm, tap enter.

Copying user profiles

Copying user profiles creates a copy of an existing user profile with the same settings defined in the user profile.

- 1 Go to **Settings > User settings**.
- 2 Tap on the user profile to be copied.
The selected user profile is shown in orange.
- 3 Tap **Clone**.
- 4 Enter a name for the new user profile.
- 5 To confirm, tap enter.

Deleting user profiles

The currently active user profile cannot be deleted. The user profile **Unnamed User** is the default user and cannot be deleted or edited.

- 1 Go to **Settings > User settings**.
- 2 Tap on the user profile to be deleted.
The selected user profile is shown in orange.
- 3 Tap **Delete**.
A pop-up window appears.
- 4 To confirm deletion of the user profile, tap **Delete**.

4.6.4 Instrument settings

Notifications and LED feedback for errors cannot be disabled.

The user can change the following settings for the respective user profile:

- information notifications,
- break state notifications,
- LED feedback of the instrument, and
- display brightness.

Tap the respective toggle switch to enable or disable the notifications or LED feedback. To receive further information about the respective setting, tap on the info icon.

Move the slider to increase or decrease the display brightness.

4.6.5 Software update

New software versions can be installed from a USB flash drive by the user. Make sure that the USB flash drive is formatted as exFAT for compatibility with the operating system. If required, change the format on a PC.

To update the Miltenyi Biotec program database and import new Miltenyi Biotec programs, see **Importing programs on page 65**.

- 1 Insert the USB flash drive to the USB port of the gentleMACS Octo Dissociator with Heaters.
- 2 Go to **Settings > Software update**.
- 3 Tap **Install**.
- 4 Choose the new software version to be installed from the USB flash drive.
- 5 Confirm to resume installation.
The instrument system checks if the software version is compatible with the instrument and installs the software.
- 6 The instrument reboots automatically with the newly installed software version and notifies the user about successful installation.

4.7 LEDs

Various statuses of the instrument are indicated by LEDs illuminating the Safety Shield and the gentleMACS Tubes. The LED feedback can be turned off, except for error feedback. See **User settings on page 67**.

LED status	Instrument status
Blue, solid	all positions in status running
Green, solid	at least one position is in status free , partly or ready
Green, blinking	at least one position is in status done
Blue, blinking	at least one position in status paused or break
Red, blinking	an error occurred. See Troubleshooting table on page 77 .

Table 4.3: Color code of the status LEDs

5

Performing runs

5.1 Running a single sample

- 1 Attach a tube upside down to the Sleeve of the respective position on the instrument. The instrument automatically detects the inserted tube and selects the position.

Insert and remove tubes in an upright position without tilting. Tilting might result in damage of the tube seal and subsequent leakage. Ensure that the tube is securely fastened to its Sleeve and socket. It must 'click' into position. Do not force the tube into the position. In case of resistance slightly turn the tube clockwise to find the right position to click in.

- 2 (Optional) If running a program including an incubation step, apply a gentleMACS Heater to the respective tube position. Slightly open the clamp of the gentleMACS Heater by pressing the upper handles and adjust it over the tube. Make sure the lower side of the gentleMACS Heater is facing towards you therefore allowing the electrical contact to close tightly. The instrument automatically detects the attached gentleMACS Heater.

Make sure that the gentleMACS Heater is securely fastened around the tube and to the socket. Do not use gentleMACS Heaters without a tube.

- 3 Tap on the desired program to run in the programs list.
The selected program is applied to the selected position box. The position status changes from **partly** to **ready**.
- 4 Tap the local start symbol in the position box to start the run.
The progress bar and timer indicate the remaining time until the program is done.
- 5 On completion of the program, the status of the position box changes to **done**.
- 6 Remove the tube from the tube position.
The status of the tube position changes to **free**.

5.2 Running multiple samples simultaneously

Up to eight samples can be run simultaneously using the same or different programs.

In this example, eight samples will be processed using the same program without a heating step.

- 1 Tap **Select all** to select all free position boxes in the **Home** hub.
- 2 Tap on the desired program to run in the programs list. The program is applied to all selected position boxes.
- 3 Attach tubes upside down to the Sleeves of the respective positions on the instrument. The instrument automatically detects the inserted tubes.

Insert and remove tubes in an upright position without tilting. Tilting might result in damage of the tube seal and subsequent leakage. Ensure that the tube is securely fastened to its Sleeve and socket. It must 'click' into position. Do not force the tube into the position. In case of resistance slightly turn the tube clockwise to find the right position to click in.

- 4 Press the **Start** button to start the run on all positions in the status **ready**.
The progress bar and timer indicate the time remaining for each position box.
- 5 On completion of the program, the status of the position boxes changes to **done**.

For further processing, use the **New** button to reset the position boxes from the **done** status into the **partly** status to assign a new program.

- 6 Remove the tubes from the tube positions.
The status of the position boxes changes to **free**.

5.3 Running a perfusion program

Before running a perfusion program, install the gentleMACS Perfusion Sleeves. For more information on the gentleMACS Perfusers and gentleMACS Perfusion Sleeves, refer to the respective data sheet.

- 1 Remove the gentleMACS Sleeve from the position you want to run a perfusion program.
To remove the Sleeve, pull it straight up.
- 2 Place the gentleMACS Perfusion Sleeve on the vacant metal pin.
- 3 Install the Sleeve by pressing it down completely.
- 4 After installation, the spring must be relaxed again.
- 5 Repeat step 1–4 for each position you want to run a perfusion program on.
- 6 Obey the steps described in the respective data sheet of the respective MACS Perfusion kit used.

For perfusion programs, manual steps must be performed during the **pause** status of the run.

5.4 Pausing and resuming samples

To pause a running sample, do one of the following:

- Tap the local **Pause** button of the respective position box. The status of the position changes from **running** to **paused**.
- Tap the global **Pause** button. All running samples will be paused. The status of all affected positions changes from **running** to **paused**.

To resume a paused sample, do one of the following:

- Tap the local **Start** button of the respective position box. The status of the position changes from **paused** to **running**.
- Tap the global **Start** button. All running samples will be paused. The status of all affected positions changes from **paused** to **running**.

To resume a break, tap the local **Start** button of the respective position box.

5.5 Aborting a running sample

- 1 Tap on the position boxes with runs to abort.
- 2 Tap **Abort**.
- 3 Confirm the notification by tapping **Abort**. The status of the selected position boxes changes from **running** to **done**.

6

Maintenance

WARNING

Contamination or infection could result in death or serious injury depending on the material used.

- Wear personal protective equipment (such as gloves, safety glasses, etc.) as indicated in the safety data sheet for the particular substance.

WARNING

Electric shock, short circuit, overheating, fire, and explosion could result in death or serious injury.

- Unplug the instrument before cleaning it.
- Use only small amounts of cleaning agents on a soft cloth to wipe the instrument. Do not spray or pour liquid cleaning agents onto or into the instrument.

Larger amounts of accidentally spilled liquid are automatically collected in the Trough of the gentleMACS Octo Dissociator with Heaters. Use a pipette to aspirate the liquid before removing the Trough for decontamination and cleaning.

Instrument parts wear over time, especially Sleeves. Depending on the sample material and frequency of use, these parts require regular maintenance and/or replacement. Contact Miltenyi Biotec Technical Support regarding spare parts. Miltenyi Biotec also offers service contracts for the gentleMACS Octo Dissociator with Heaters. Visit www.miltenyibiotec.com/gentlemacs-service for further information.

6.1 Decontamination and cleaning

In case of spillage or contamination, clean the instrument appropriately.

For disinfection, wipe the instrument with 70% ethanol or 70% isopropanol.

Clean the instrument only with cleaning agents that are noncorrosive and not damaging the plastic housing. Suitable cleaning agents include household detergents, 70% ethanol, and 70% isopropanol. Do not use acetone or any aggressive agents. If in doubt, if a certain cleaning agent is suitable for disinfection and/or cleaning the gentleMACS Octo Dissociator with Heaters, contact Miltenyi Biotec Technical Support.

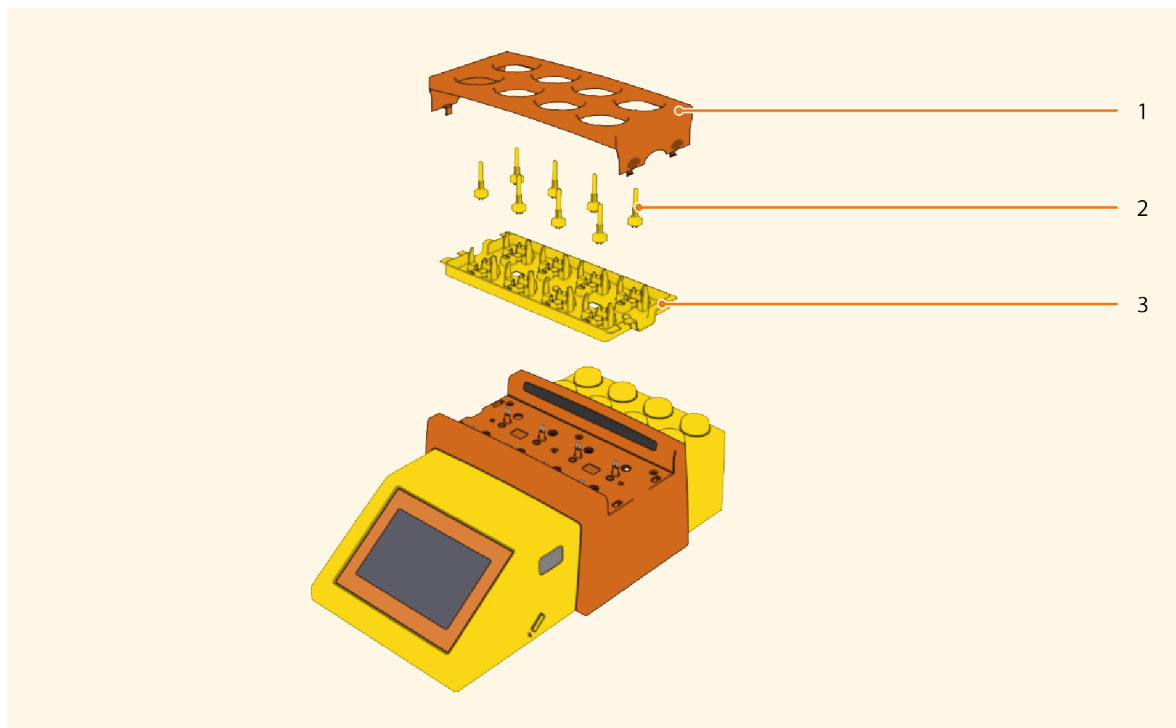


Figure 6.1: Steps 2-4 of the gentleMACS Octo Dissociator with Heaters disassembly for cleaning

- 1** Unplug the power cable from the electrical outlet before cleaning the instrument.
- 2** Remove the Safety Shield (1).
- 3** Remove the Sleeves from the Sleeve holders (2).
- 4** Remove the Trough from the baseplate (3).
To remove the Trough, pull on one side. Do not pull on both sides at the same time.
- 5** Carefully wipe the surface of the instrument and all removed parts with a cloth soaked with a detergent-containing aqueous solution, 70% ethanol or 70% isopropanol.
- 6** Repeat the procedure with another cloth soaked with distilled water.
- 7** Reassemble the removed parts. Start with the Trough, followed by the Sleeves, and the Safety Shield. Make sure that the orientation of the Trough and Safety Shield is correct.

7

Troubleshooting

7.1 Troubleshooting table

Issue	Possible reason	Solution
Liquid droplets appear in the Trough.	Tube is not closed properly.	Close the tube tightly beyond first resistance.
	Sample is jammed between the cap and the tube and damages the seal. This might cause liquid to run through the seal.	The top area of the cap and the tube must be perfectly clean for proper functioning of the seal.
	Tube seal is leaky.	Replace the tube.
	Sleeve is worn.	Exchange Sleeve.
Tube is blocked during a run.	Inappropriate sample material.	Check the respective data sheet for technical specifications of the tubes.
Program is automatically aborted and the instrument displays the message "Motor is blocked. Program was aborted."	If the motor is blocked due to a high resistance of the sample material, the instrument will try three times to get started again	Process a smaller amount of tissue, or use a different gentleMACS Program.
	If the blockage can be resolved, the instrument will continue the run of the program. If the blockage cannot be resolved, the program will automatically be aborted.	Check if tissue is trapped between the stator and rotor. Release tissue, reinstall tube, and tap Continue to resume the program.
Tube comes off the instrument.	Tube is not correctly mounted into the snap-fit of the Trough.	Ensure correct installation of the tube.
	Tube is not closed properly.	Close the tube tightly beyond first resistance.
A warning message appears in a pop-up window when saving an edited program. "Input error - Maximum rounds per run (3200) exceeded!"	The duration of the program exceeds 3,200 rounds per run (rpr). It is not recommended to run programs exceeding this limitation! Miltenyi Biotec does not guarantee proper function of the instruments and disposables above this value.	Press OK to save the program. Press Abort to re-edit the program.

Issue	Possible reason	Solution
New program containing iterations cannot be saved. The instrument displays an error message with the cause of the error.	"Loop command is faulty. End loop command is missing." indicates that the end loop command has not been specified.	Close iterations by adding an end loop command.
	"Loop command is faulty. The command is nested." indicates that there are more than one loop commands.	Use only one loop command and close the iteration by adding an end loop command
	"Loop command is faulty. Loop has no body." indicates that there is no command between the start and end loop command.	At least one program step must be included between a start and end loop command. Add steps and define commands that shall be iterated.
A warning message "The heater was removed!" appears in a pop-up window while running a heaters program.	The heater was removed.	Reinstall heater.
	The heater is not installed properly.	Make sure that the heater is installed properly. Carefully clean the heater contacts of the instruments and the resp. heater using a cloak soaked with water or 70% ethanol.
	The electrical contacts of the instrument or the heater are dirty or corroded.	Carefully check the heater for signs of damage. If no visible signs of damage can be detected, switch the instrument off and on again and retry to run the program.
		Contact Miltenyi Biotec Technical Support.
Software for updating the Miltenyi Biotec program database is not detected.	The Software update tab is used for updating the Miltenyi Biotec program database.	Updating the Miltenyi Biotec program database is not a software update. To import new Miltenyi Biotec programs, go to the Programs hub and tap Import. See Importing programs on page 65.
USB flash drive is not recognized.	The USB flash drive has the wrong format.	Format the USB flash drive as exFAT.

Table 7.1: Troubleshooting for the gentleMACS Octo Dissociator with Heaters

7.2 Exporting log files

Log files can help Miltenyi Biotec Technical Support with troubleshooting. Log files can be exported to a USB flash drive. Make sure that the USB flash drive is formatted as exFAT for compatibility with the operating system. If required, change the format on a PC.

- 1 Insert the USB flash drive to the USB port of the gentleMACS Octo Dissociator with Heaters.
- 2 Go to **Settings > Logfile export**
- 3 Tab **Export logfile** to start the export.
- 4 After notification that the export is finished, remove the USB flash drive from the instrument.

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Technical support

For technical support, contact your local Miltenyi Biotec representative or Miltenyi Biotec Technical Support at Miltenyi Biotec headquarters:

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51429 Bergisch Gladbach
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Phone: +49 2204 8306 3803
technicalsupport@miltenyi.com

Visit **www.miltenyibiotec.com** for local Miltenyi Biotec Technical Support contact information.

Technical data and specifications

Technical data	Specification
Colors	Yellow / orange
Dimensions (width x depth)	285 mm × 496 mm
Height	188.5 mm (without heaters) 245 mm (with heaters)
Weight	11.8 kg
Main power	
Power consumption	450 W
Supply voltage	100–240 V~, 50/60 Hz
Fuses	2 x 3.15 AH, 250 V
Motor	
Rotational speed	20–4,000 rpm
Rotational direction	Clockwise or counterclockwise
Rotational acceleration	100 r/s ²
Torque	Max. 150 mNm; Overload restriction over the range of 200–4,000 rpm
Conditions of operation	
Working temperature without use of heaters	+5 °C to +35 °C
Working temperature with use of heaters	+18 °C to +30 °C
Humidity	15–85%, relative, noncondensing
Altitude	Max. 2,000 m
Storage temperature	-15 °C to +70 °C
Ports	1 × USB 2.0 1 × Ethernet (10/100/1000 MBit/s) 1 × CAN (1 MBit/s)
RAM	4 GB DDR3L
Mass storage	32 GB mSATA SSD
Mainboard battery	Button cell, lithium metal
Monitor	7" TFT LCD touchscreen
Maximum number of programs	500
Number of heatable positions	8

Technical data	Specification
Maximum noise emission	
Sound pressure level at workstation	85 dB(A) +/- 2.5 dB(A)
Sound power level	91 dB
Measurement operation conditions: 8x C Tubes containing 500 µL of liquid, processed at 4,000 rpm	
Working temperature heaters	37 °C

Table 9.1: Technical data of the instrument

The gentleMACS™ Octo Dissociator with Heaters is classified as protection class I device and must be plugged into a grounded electrical outlet.

Note that for USA and Canada, the main power supply cord and plug of the instrument shall comply with the following specifications: UL listed and KAM cord, minimum type SJ, minimum 18 AWG, 3 conductors. Rated for a minimum temperature of 60 °C. Provided with grounding-type (NEMA 5-15P) attachment plug, rated 125 VAC, 10 A. Opposite end terminates in IEC 320-style connector, rated 125 VAC, 10A.

Supply voltage fluctuations up to +/- 10% of the nominal voltage.

Transient overvoltages present on the mains supply: category II.

The instrument is suitable for pollution degree 2 environments.

The instrument has been designed for a lifetime of 10 years.

9.1 FCC compliance statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications made to this equipment not expressly approved by the party responsible for compliance may void the FCC authorization to operate this equipment. For other safety considerations, refer to the product label or visit www.miltenyibiotec.com. Design and specifications are subject to change without notice.

9.2 EC/EU Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Miltenyi Biotec B.V. & Co. KG
Friedrich-Ebert-Straße 68
51429 Bergisch Gladbach
Germany

This declaration relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.

The declaration of conformity refers to the machinery identified as follows:

Description: Laboratory equipment
Model: gentleMACS Octo Dissociator with Heaters (A44109)

The machinery complies with all essential requirements of the following directives:

2006/42/EC Machinery
2011/65/EU Restriction of the use of certain hazardous substances in electrical & electronic equipment
2014/30/EU Electromagnetic compatibility

The machinery is in conformity with the following harmonized standards:

EN 61010-1:2010
EN 61010-2-010:2014
EN 61010-2-051:2015
EN 61326-1:2013

Person authorized to compile the relevant technical documentation:

Dr. Bernd Schröder
Global Head Regulatory Affairs
Miltenyi Biotec B.V. & Co. KG
Friedrich-Ebert-Straße 68
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9.3 UK Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the manufacturer:

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This declaration relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.

The declaration of conformity refers to the machinery identified as follows:

Description: Laboratory equipment
Model: gentleMACS Octo Dissociator with Heaters (A44109)

The machinery complies with all essential requirements of the following legislations:

Supply of machinery (Safety) regulations 2008
The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012
Electromagnetic Compatibility Regulations 2016

The machinery is in conformity with the following UK designated standards:

EN 61010-1:2010
EN 61010-2-010:2014
EN 61010-2-051:2015
EN 61326-1:2013

Person authorized to compile the relevant technical documentation:

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Legal notes

10.1 Limited warranty

Except as stated in a specific warranty statement which may accompany this product or as otherwise agreed in writing by an authorized representative of Miltenyi Biotec, Miltenyi Biotec's warranty to you, the original purchaser and end user ("you" or "your"), with respect to the product accompanied by this limited warranty shall be subject to the following provisions and the general terms and conditions of sale of the company within the Miltenyi Biotec group which supplied the product in effect at the date of purchase. Those terms and conditions of sale may vary by country and region. Nothing in this document should be construed as constituting an additional warranty.

Miltenyi Biotec warrants that this product will operate or perform substantially in conformance with Miltenyi Biotec's published specifications and be free from material defects in material and workmanship, when subjected to normal, proper, and intended usage by properly trained personnel, for the period of time set forth in the product documentation or package inserts accompanying the product (the "Warranty Period").

Miltenyi Biotec agrees, during the Warranty Period, to repair or replace, at Miltenyi Biotec's option, the defective product so as to cause the same to operate in substantial conformance with said published specifications; provided that you shall (a) promptly notify Miltenyi Biotec in writing upon the discovery of any nonconformity or defect, which notice shall include the product model and serial number (if applicable) and details of the warranty claim; and (b) return the nonconforming or defective product to Miltenyi Biotec, freight prepaid, only after receipt of a Return Material Authorization ("RMA") from Miltenyi Biotec, which may include biohazard decontamination procedures and other product-specific handling instructions, if applicable.

Miltenyi Biotec shall have no obligation to make repairs, replacements, or corrections to the product or any component thereof required, in whole or in part, as the result of (i) normal wear and tear, (ii) improper handling, installation, operation, storage, service, maintenance, or repair, (iii) failure to follow the instructions, cautions, warnings, and notes set forth in the product documentation provided with the product or provided by Miltenyi Biotec from time to time, (iv) abnormal use, misuse, neglect, abuse, mishandling, misapplication, modification, or alteration of the product, (v) use of the product in a manner for which it was not designed, (vi) causes external to the product such as, but not limited to, power failure or electrical power surges, (vii) use of the product in combination with equipment, accessories, consumables, or software not supplied or approved by Miltenyi Biotec, or (viii) accident, disaster, or acts of God. ANY INSTALLATION, MAINTENANCE, REPAIR, SERVICE, OR ALTERATION TO OR OF, OR OTHER TAMPERING WITH, THE PRODUCT PERFORMED BY ANY PERSON OR ENTITY OTHER THAN MILTENYI BIOTEC AUTHORIZED PERSONNEL WITHOUT MILTENYI BIOTEC'S PRIOR WRITTEN APPROVAL, OR ANY USE OF REPLACEMENT PARTS NOT SUPPLIED BY MILTENYI BIOTEC, SHALL IMMEDIATELY VOID AND CANCEL ALL WARRANTIES WITH RESPECT TO THE AFFECTED PRODUCT.

Miltenyi Biotec's warranty does not cover products sold AS IS or WITH ALL FAULTS, or which had its serial number defaced, altered, or removed, or any consumables or parts identified as being supplied by a third party.

Miltenyi Biotec must be informed promptly if a claim is made under this limited warranty. If a material or manufacturing defect occurs within the Warranty Period, Miltenyi Biotec will take the appropriate steps, at Miltenyi Biotec's option, to make repairs, replacements, or corrections to the product or any component thereof as may be required to restore the full usability of your product. If Miltenyi Biotec determines that a product for which you have requested warranty services is not covered by the warranty hereunder, you shall pay or reimburse Miltenyi Biotec for all costs of investigating and responding to such request at Miltenyi Biotec's then prevailing time and materials rates. If Miltenyi Biotec provides repair services or replacement parts that are not covered by this warranty, you shall pay Miltenyi Biotec therefor at Miltenyi Biotec's then prevailing time and materials rates.

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